April 14, 1978 SECY-78-211

COMMISSIONER ACTION

For: The Commissioners

From: Lee V. Gossick
Executive Director for Operations

Subject: FINAL RECOMMENDATIONS OF THE TASK FORCE ON REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

Purpose: To inform the Commission of the Public Comments on NUREG-0301 and the Task Force's recommendations to the Commission for seeking legislative authority to regulate NARM and to request approval to draft such legislation.

Category: This paper covers a major policy matter.

Issue: Whether NRC should regulate naturally occurring and accelerator-produced radioactive materials.

Discussion: BACKGROUND

NRC was requested by the Agreement States and by the Conference of Radiation Control Program Directors to look into the matter of regulating naturally occurring and accelerator-produced radioactive materials. On March 4, 1976, the Commission approved formation of an internal task force to review this matter (SECY-76-28).

The task force includes representatives from SP, ELD, IE and SD. The Chairman is Donald A. Nussbaumer of NMSS. Technical coordination is being provided by Joel O. Lubenau, SP. In addition, the Conference, the Agreement States, FDA's Bureau of Radiological Health, and EPA provided resource persons to the task force.

Contacts:
Donald A. Nussbaumer, NMSS
427-4130
and
Joel O. Lubenau, SP
[redacted]7767

Discussion: (continued)

An Information Report (SECY-77-155) was sent to the Commissioners following preparation of a draft task force report. In June, 1977, the Commission approved publication of the task force report for public comment (SECY-77-155A). The report was published in July, 1977 (NUREG-0301) and a Federal Register notice was published and a news release was issued announcing its availability and inviting public comment for a sixty-day period (Appendix A). The report was given wide distribution. Copies were sent to the following addressees with a request for comments:

56-State and Territorial Health Officers (Appendix B);

55-State and local Radiation Control Program Directors (Appendix C);

22-Federal Agencies identified in the report as having an interest, or potential interest, in regulating these materials, (Appendix D); and

72-Presidents of firms which are manufacturers and distributors of products containing NARM (Appendix E).

Copies were also sent to the Southern and Western Interstate Nuclear Boards and to the National Council on Radiation Protection and Measurements under a cover letter requesting comment. Copies of the news release and Federal Register notice were sent to professional societies. In all, over 200 persons representing Government, industry and professional groups were individually contacted.

The task force found that naturally occurring and accelerator-produced radioactive materials (NARM) are widely used -- excluding those who would be exempt from licensing, about 30% of all users of radioactive materials use NARM. There are an estimated 6,000 users of NARM at present. The use of accelerator-produced radioisotopes, particularly in medicine, is growing rapidly. One NARM isotope, radium-226, is one of the most hazardous of radioactive materials. It is used by about 20% of all radioactive material users. About 85,000 medical treatments using radium occur each year.

The task force also found that the regulation of NARM is fragmented, non-uniform and incomplete at both Federal and State levels.

Discussion: (continued) As a result of its findings, the task force recommended the following:

"With respect to new or improved NRC actions, it is recommended that the Commission seek legislative authority to:

"A. License and regulate NARM as follows:

"1. In any activity that is part of, or in support of, the nuclear fuel cycle regulated by NRC.

"2. In any activity where: (a) NARM is manufactured (e.g., production of accelerator radioisotopes, the separation of radium and radium daughters, and radon generators); (b) NARM is incorporated into sources or devices* subject to licensing; or (c) NARM is used in the same manner as radioactive materials** subject to NRC regulation.

"3. In any activity where NARM is introduced into products intended for distribution to persons exempt from licensing. (It is intended that this include only activities where the introduction of NARM is deliberate and has as a purpose the utilization of its radioactive properties.)

"4. In any activity involving the management of NARM wastes which result from licensed activities.

"B. Extend authority under Section 274 of the Atomic Energy Act to relinquish authority to regulate NARM (except control of the distribution of NARM to persons exempt from licensing) to Agreement States and to other States having existing regulatory programs for NARM which are determined to be adequate and to be compatible."

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* e.g., sealed sources such as gauging devices, radiography sources, oil well logging sources and devices, etc.

** Radioactive materials used in normal form or loose form as, for example, in medical diagnosis.

Discussion: (continued)

SUMMARY OF PUBLIC COMMENTS

The comment period expired September 19, 1977. Twenty-five (25) comments were received. A detailed analysis of the comments is presented in Appendix F. Twenty-one (21) respondents expressed varying degrees of support for the task force recommendation. These included all of the 6 States and 5 of the 7 Federal Agencies who commented. Two respondents provided comments but took no position on the recommendation. One response received from industry (Westinghouse) and one received from a Federal Agency (EPA) opposed the recommendation. EPA commented that it has adequate existing authority to regulate NARM.

FDA's Bureau of Radiological Health supported the recommendation in principle but suggested deferring action until a voluntary FDA-State effort to control NARM has been implemented and its effectiveness has been evaluated.

No responses were received from the 15 other Federal Agencies contacted including the Occupational Health and Safety Administration or the Consumer Product Safety Commission.

Comments which qualified the support of the recommendation were received from 13 of the 21 who supported it. The most frequent of these expressed concern over the need for adequate numbers of NRC staff to handle the regulation of NARM. Three (3) comments were received which stated the data in the report does not support the recommendation. (Two of these were from commentors opposing the recommendation [Westinghouse and EPA] and the third from FDA.) (The problem here is a paucity of data due to fragmentary regulation among Federal and state agencies.) Two Federal Agencies (MESA and CDC-NIOSH) felt clarification was needed on the regulatory role of NRC with respect to mines.

Two of the comments supporting the recommendation were received from NCRP and NBS. NCRP supported efforts to obtain authority for NRC to regulate accelerator-produced radioactive material but reserved an endorsement of the recommendation as applied to naturally

Discussion: (continued) occurring radioactive materials until there was further clarification of the roles of NCRP, EPA, NRC and other interested parties. NBS fully supported the recommendation of the task force and noted the proposed authority was exactly the same as NBS proposed when it commented to OMB on EPA's proposed bill to regulate naturally occurring radioactive materials, in early 1977.

The Department of Energy supports the recommendation.

The staff took note of State comments on an NRC task force study concerning the Agreement States Program. A draft report was published in August, 1977 as NUREG-0299 (SECY-77-437). One conclusion of that draft report was that only one other NRC study (on low-level radwaste management [SECY-77-489]) might impact upon Agreement States. In their comments on the draft report, Kentucky and Colorado sharply disagreed and identified the NARM study as another which would impact upon States. As a result of these comments, the Final Task Force Report on the Agreement States Program (NUREG-0388, SECY-77-621) included an endorsement of the recommendation of the NARM task force that NRC seek authority to regulate these materials.

The NARM task force noted that the NARM study interfaces, in part, with the uranium milling GEIS, particularly control of mill tailings. The Commission has approved a staff proposal to draft proposed legislation to give NRC authority to regulate naturally occurring radioactive materials associated with mill tailings in non-Agreement States (SECY-77-303A). Such legislation, in principle, would be consistent with the NARM task force recommendation as it affected mill tailings.

STAFF CONSIDERATION OF THE TASK FORCE RECOMMENDATION

In considering the task force recommendation, the staff analyzed the findings in NUREG-0301, the public comments, and other information contained in Appendix G. The staff evaluation of the recommendation and other options available to the Commission is presented in Appendix H. The staff's conclusions, based upon this evaluation, are summarized as follows:

Discussion:

-- Full implementation of Federal controls is needed to fill significant regulatory gaps in the control of NARM and protect the public health and safety.

-- Legislative clarification of Federal regulatory responsibilities with respect to NARM is necessary.

-- The need for some NRC authority over NARM (in mill tailings) has already been established and recognized by the Commission.

-- Federal control of NARM can most easily be accomplished by folding such materials into the existing NRC regulatory programs for byproduct, source and special nuclear materials, including the Agreement State program.

-- In light of comments received, assertion by NRC of regulation of NARM, would not be objected to by other Federal Agencies, with the likely exception of EPA. (See Appendix F, Analysis of Public Comments on NUREG 0301.)

-- The impact upon NRC to implement the recommendation of NUREG-0301 will be relatively modest: An additional 7 person-years of professional effort will be needed to handle the additional routine workload. The dollar cost would be about $500,000 (Appendix I).

It should be noted that the Senate Committee on Governmental Affairs recently completed a study on Federal Regulation and published a report in December, 1977. With respect to radiation matters, the report stated that "Radiation safety is marked by too many agencies administering too many laws, adopted in a piecemeal approach." The report quotes liberally from the NARM Task Force report in discussing NARM. The report recommends that EPA be given authority to take over as lead agency in radiation protection matters. The NRC staff was contacted by the Committee staff during preparation of its report concerning the general issue of NARM and, specifically, the disposition by the Commission of the NARM Task Force recommendation. The staff believes a Commission position on this issue should be established in the near future.

Recommendations: The staff recommends that the Commission approve:

1. Preparation by the staff of a draft bill giving NRC regulatory jurisdiction over NARM.

2. Transmittal of letters (substantially as shown in Appendix K) to the appropriate Congressional Committees informing them of the decision.

3. Transmittal of letters (substantially as shown in Appendix J) to State and Territorial Health Officers, Radiation Control Program Directors, Federal Agencies, and manufacturers and distributors of NARM informing them of decision.

Coordination: The Office of the Executive Legal Director has no legal objections to the contents of this paper or the proposed letters. ELD notes and OPE concurs in the following: Any legislation designed to reduce duplication and overlap in regulatory authority over NARM and vest additional regulatory authority in NRC would deprive EPA of some of its existing authority. Given the impact which extension of NRC jurisdiction to include NARM would have on the jurisdiction of other agencies, consideration might be given by the Commission to a more comprehensive reorganization of existing radiation protection authorities. Whether NRC efforts along these lines are confined to NARM or are more ambitious, some controversy will likely result. To the extent the recommendation would apply to uranium mill tailings, OPE does not concur. OPE comments are responded to in Enclosure L.

The Offices of State Programs, Nuclear Material Safety and Safeguards, Inspection and Enforcement, and Standards Development concur in this paper. OGC has no comments.

Lee V. Gossick
Executive Director for Operations

Enclosures:
See next page

Enclosures:
Appendix A - Federal Register notice, NUREG-0301
B - D.A. Nussbaumer July 1977 ltr to State and Territorial Health Officers Regarding NUREG-0301
C - G. W. Kerr July 1977 ltr to All Agreement and non-Agreement States Regarding NUREG-0301
D - D.A. Nussbaumer July 1977 ltr to Federal Agencies Regarding NUREG-0301
E - D.A. Nussbaumer July 1977 ltr to Presidents of NARM Manufacturing and Distributing Firms
F - Analysis of Public Comments on NUREG-0301
G - Information Considered by the Staff Subsequent to NUREG-0301
H - Evaluation of Options
I - Estimation of NRC Resources Needed
J - Letters to State and Territorial Health Officers, Radiation Control Program Directors, Federal Agencies and NARM Manufacturers and Distributors
K - Letters to Congressional Committees
L - OPE Comments and Response

Commissioners' comments should be provided directly to the Office of the Secretary by close of business Monday, May 1, 1978.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT April 21, 1978, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

This paper is tentatively scheduled for a briefing at an Open Meeting during the Week of April 24, 1978. Please refer to the appropriate Weekly Commission Schedule, when published, for a specific date and time.

DISTRIBUTION
Commissioners
Commission Staff Offices
Exec Dir for Operations
Secretariat

APPENDIX A

FEDERAL REGISTER NOTICE, NUREG-0301

NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

Task Force Report

A Nuclear Regulatory Commission Task Force has completed a review of the matter of regulation of naturally occurring and accelerator-produced radioactive materials. These materials are not presently regulated by NRC because they do not come within the scope of the definitions of nuclear materials in the Atomic Energy Act. The scope of the study, as prescribed for the Task Force, was limited to review of Federal and State regulation of naturally occurring and accelerator-produced radioactive materials. Sources of ionizing radiation involving radiation-producing equipment, such as X-ray machines, were not included in the study.

The conclusions and recommendations of the Task Force are as follows:

1. The regulation of naturally occurring and accelerator-produced radioactive material (NARM) is fragmented, non-uniform and incomplete at both the Federal and State level. Yet, these radioactive materials are widely used—excluding those who would be exempt from licensing, about 30% of all users of radioactive materials use NARM. There are an estimated 6,000 users of NARM at present. The use of accelerator-produced radioisotopes, particularly in medicine, is growing rapidly.

2. One NARM radioisotope—^{226}Ra—is one of the most hazardous of radioactive materials. ^{226}Ra is used by about ⅓ of all radioactive material users. Also, there are about 85,000 medical treatments using ^{226}Ra each year.

3. All of the 25 Agreement States and 5 non-Agreement States have licensing programs covering NARM users. The Agreement States' programs for regulating NARM are comparable to their programs for regulating byproduct, source and special nuclear materials under agreements with NRC. But there are 7 States who exercise no regulatory control over NARM users, and the remaining States have control programs which are variable in scope. There are no national, uniformly applied programs to regulate the design, fabrication and quality of sources and devices containing NARM or consumer products containing NARM which are distributed in interstate commerce.

4. Naturally occurring radioactive material (except source material) associated with the nuclear fuel cycle is only partially subject to NRC regulation, i.e., when it is associated with source or special nuclear material being used under an active NRC license.

5. Because of the fragmented and non-uniform controls over radium and other NARM, information on the impact of the use of NARM on public health and safety is fragmentary. Thus, it is difficult to know, in an overall sense, whether proper protection is being provided to workers and the public. A number of the incidents involving NARM and other data, however, which have come to the attention of public health authorities give definite indications of unnecessary and possibly excessive radiation exposure of workers and the public.

Recommendation

The Task Force recommends that the NRC seek legislative authority to regulate naturally occurring and accelerator-produced radioactive materials for the reason that these materials present significant radiation exposure potential and present controls are fragmentary and non-uniform at both the State and Federal level.

The Commission believes that opportunity for public comment should be afforded before the Commission reaches any decision on the Task Force recommendations. All interested persons who desire to submit written comments on the report and its recommendations should send them by September 19, 1977, to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Copies of the complete report are available for inspection and copying at the Commission's Public Document Room at 1717 H Street NW., Washington, D.C., and at the Commission's local Public Document Rooms. Copies of the comments received in response to this notice will be placed in the Commission's Public Document Room in Washington, as received. Single copies of the report may be obtained without charge, to the extent of supply, by writing to the Division of Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Copies of the report NUREG-0301 will be available for sale at the National Technical Information Service, Springfield, Va. 22161.

Dated at Washington, D.C., this 8th day of July 1977.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc.77-21030 Filed 7-20-77;8:45 am]

APPENDIX A

APPENDIX B

D.A. Nussbaumer July 1977 ltr to State and Territorial Health Officers Regarding NUREG-0301

7/8/77

Ira L. Myers, M.D., State Health Officer
State Department of Public Health
State Office Building
Montgomery, AL 36104

Dear Dr. Myers:

A U.S. Nuclear Regulatory Commission (NRC) Task Force has recently completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC. NRC was requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC should seek such authority. The Commission, recognizing the need for input from potentially affected persons and organizations, including State Agencies, as part of its deliberative process is making the report available for public review and comment. A Federal Register notice will be published concerning this action.

A copy of the Task Force report is enclosed. I am bringing it to your attention because the States' present regulatory role with respect to these materials could be affected if the recommended action is undertaken. A copy of this report has also been sent to the head of the radiological health program in your Agency.

Should you have any comments, please send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Should you have any questions on this matter that you would wish to discuss, please contact me or Joel Lubenau, Office of State Programs.

Sincerely,

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material Safety
and Safeguards

APPENDIX B

APPENDIX C

G.W. Kerr July 1977 ltr to All Agreement and Non-Agreement States Regarding NUREG-0301

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 15 1977

Ref: SA/JOL

All Agreement States and Non-Agreement States

NRC TASK FORCE ON THE REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS

I have attached a copy of an NRC Task Force report on the above subject. We are also sending copies to each State Health Officer (or equivalent).

NRC was requested by the Agreement States in 1974 and by the Conference of Radiation Control Program Directors in 1975 to bring naturally occurring and accelerator-produced radioactive materials under its jurisdiction. In response to these requests, NRC, in January 1976, established a task force to review the matter of regulation of these materials. Resource persons from the Agreement States, non-Agreement States, FDA Bureau of Radiological Health and EPA, also participated.

The Task Force recommended NRC should seek legislative authority to regulate these materials.

Because of the recognized need to properly interface with other Federal and State agencies on this matter, NRC is making the report available to government agencies and to the public for comment.

A Federal Register notice announcing availability of the report and requesting public review and comment will be published shortly. We would appreciate receiving a copy of any comments you may file concerning the report.

G. Wayne Kerr, Assistant Director
for State Agreements Program
Office of State Programs

Enclosures:
As stated

APPENDIX C

APPENDIX D

D.A. Nussbaumer July 1977 ltr to Federal Agencies Regarding NUREG-0301

JUL 29 1977

Eula Bingham, Ph.D.
Assistant Secretary for Occupational
Safety & Health
Department of Labor
Third Street & Constitution Avenue, N.W.
Washington, D.C. 20210

Dear Dr. Bingham:

A U.S. Nuclear Regulatory Commission (NRC) Task Force has recently completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. The NRC does not have legislative authority to regulate these materials. NRC was requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC should seek such authority. The Commission, recognizing the need for input from potentially affected persons and organizations, including Federal Agencies, is making the report available for public review and comment. A Federal Register notice was published on July 14, 1977 concerning this action.

A copy of the Task Force report is enclosed. I am bringing it to your attention because your Agency was identified by the Task Force as an Agency having some regulatory interest, directly or indirectly, in this matter.

Should you have any comments, please send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Sincerely,

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material Safety
and Safeguards

APPENDIX D

ADDRESSEE LIST

David H. Link, Acting Director
Bureau of Medical Devices &
Diagnostic Products
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852

Eula Bingham, Ph.D.
Assistant Secretary for Occupational
Safety & Health
Department of Labor
Third Street & Constitution Avenue, N.W.
Washington, D.C. 20210

Allan I. Roberts
Director of Office of Hazardous
Material Operations
Department of Transportation
400 Seventh Street, S.W.
Washington, D.C. 20590

Leonard Lehman
Assistant Commissioner, Regulations
& Customs
U.S. Customs Service
Department of the Treasury
15th Street & Pennsylvania Avenue, N.W.
Washington, D.C. 20220

John D. Clare, M.D.
Chief, Medical Director
Dept. of Medicine & Surgery
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Bureau of Biologics
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5600 Fishers Lane
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Howard R. Roberts, Acting Director
Bureau of Foods
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852-

Hugh F. McKenna, Acting Associate
Commissioner for Program Operations
Social Security Administration
6401 Security Boulevard
Baltimore, MD 21235

Edward J. Baier, Deputy Director
National Institute for Occupational
Safety & Health
5600 Fishers Lane
Rockville, MD 20852

William C. Watson, Jr.
Assistant Director for Operations
Center for Disease Control
1600 Clifton Road, N.E.
Atlanta, GA 30333

Barbara Ludden
Executive Assistant to the Chairman
Consumer Product Safety Commission
1750 K Street, N.W.
Washington, D.C. 20207

Edward V. Dorrey
Senior Assistant Postmaster General,
Operations
U.S. Postal Service
Washington, D.C. 20260

J. Thomas Rosch, Director
Bureau of Consumer Protection
Federal Trade Commission
Washington, D.C. 20580

James M. Day, Administrator
Mining Enforcement & Safety Administration
Department of the Interior
Washington D.C. 20240

L. L. Mitchell, Acting Executive Director
Federal Supply Service
General Services Administration
Washington, D.C. 20406

James R. Cowan, M.D.
Assistant Secretary of Defense
(Health & Environment)
Department of Defense
The Pentagon
Washington, D.C. 20301

Warren K. Sinclair, President
National Council on Radiation
Protection & Measurements
7910 Woodmont Avenue
Bethesda, MD 20014

John C. Villeforth, Director
Bureau of Radiological Health (HFX-1)
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20852

William D. Rowe, Ph.D., Deputy
Assistant Administrator for
Radiation Programs
U.S. Environmental Protection Agency
401 M Street, S.W
Washington, D.C. 20460

James E. Leiss, Ph.D., Director
Center for Radiation Research
National Bureau of Standards
Washington, D.C. 20234

James L. Liverman, Assistant
Administrator
Energy Research and Development
Administration
20 Massachusetts Avenue, N.W.
Washington, D.C. 20545

Rauer H. Meyer, Director
Office of Export Administration
Department of Commerce
Washington, D.C. 20230

APPENDIX E

D.A. Nussbaumer July 1977 ltr to Presidents of
NARM Manufacturing and Distributing Firm

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 20 1977

Dear Sir:

A U.S. Nuclear Regulatory Commission (NRC) Task Force has recently completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC. NRC was requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC should seek such authority. The Commissioners, recognizing the need for input from potentially affected persons and organizations as part of its deliberative process is making the report available for public review and comment. A Federal Register notice will be published concerning this action.

A copy of the Task Force report is enclosed. I am bringing it to your attention because your organization may be a distributor or manufacturer of these materials or devices containing these materials, and therefore has a potential interest in this matter.

Should you have any comments for the public record please send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Sincerely,

D. A. Nussbaumer

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material Safety
and Safeguards

Enclosure:
As Stated

APPENDIX E

Varian Associates
Vacuum Division
121 Hartwell Avenue
Lexington, Massachusetts 02173

Nuclear Associates
35 Urban Avenue
Westbury, New York 11590

Picker Corporation
595 Minor Road
Cleveland, Ohio 44143

Fisher Scientific Company
7722 Fenton Street
Silver Spring, Maryland 20910

General Electric
Medical Systems
4855 Electric Avenue
Milwaukee, Wisconsin 53219

Stratitrol Corporation
1030 West Ellsworth Avenue
Denver, Colorado 80323

Alnor Instrument Company
7301 North Caldwell Avenue
Niles, Illinois 60648

Minneapolis-Honeywell
Regulator Company
Minnesota Research Center
10701 Lyndale Avenue South
Bloomington, Minnesota 55420

Lustrolite Cleveland Corporation
(Presently Brilliant Electric Signs, Inc.)
1151 Main Avenue
Cleveland, Ohio 44113

New England Nuclear Corporation
549 Albany Street
Boston, Massachusetts 02118

Entronic Corporation
4348 Riverline Drive
Earth City, MO 63045

Coastal Radiation Services, Inc.
4117 Rhoda Drive
Baton Rouge, Louisiana 70816

Mine Safety Appliances Company
201 North Braddock Avenue
Pittsburgh, Pennsylvania 15208

Cenco Instruments Corporation
2600 South Kostner
Chicago, Illinois 60623

BRK Electronics, Inc.
525 Rathbone Avenue
Aurora, Illinois 60538

Atomic Products Corporation
P.O. Box 657
Center Moriches, New York 11934

Clinical Assays, Inc.
237 Binner Street
Cambridge, Massachusetts 02141

International Chemical and Nuclear
Corporation
2727 Campus Drive
Irvine, California 92664

Interex Corporation
3 Strathmore Road
Natick, Massachusetts 01760

Hochiki America, Corporation
21804 Belshire Avenue
Hawaiian Gardens, CA 90716

John U. Hidalgo
1209 Lair Avenue
Metairie, Louisiana 70003

3M Company
Minnesota Minning and Manufacturing
3M Center Street
St. Paul, Minnesota 55119

E.R. Squibb And Sons, Inc.
P.O.Box 4000
Princeton, New Jersey 08540

Fire Alert
Division of Walter Kidde
and Co., Inc.
Wheatridge, CO 80033

Vigor, Bergeon Bestfit
B. Jadow & Sons Inc.
53 W. 23rd Street
New York, New York 10010

Victoreen Instrument Company
10101 Woodland Avenue
Cleveland, Ohio 44104

Soiltest, Inc.
2205 Lee Street
Evanston, Illinois 60202

United Engineers
Automation Division of Black,
Sivalls and Bryson, Inc.
7455 East 46th Street
Tulsa, Oklahoma 74145

Glowall Corporation
Easton and Dansville Road
Willow Grove, Pennsylvania 19090

Gerald A. Leifchild
1409 West Helman Avenue
Alhambra, California 91803

Isotope Products Labs
1800 North Keystone Street
Burbank, California 91504

Radiation Detection Co.
162 Wolfe Road
Mountain View, California 94088

Kay Ray, Inc.
516 West Campus Drive
Arlington Heights, Illinois 60004

Unitec, Inc.
305 Kansas Avenue
Brewster, Kansas 67732

Campbell Pacific Nuclear Corporation
124 Buchanan Circle
Pacheco, Calfornia 94553

Environmental Sciences
2722 Campus Drive
Irvine, Calfornia 92664

Valtron, Inc.
2 Colorow Drive
P.O. Box 324
Morrison, Colorado 80465

American BioMedical
Bionuclear Division
7777 Forest Lane
Houston, Texas 75230

Columbia Scientific
Industries Corporation
P.O. box 9908
Austin, Texas 78766

Universal Security Instruments, Inc.
2829 Potee Street
Baltimore, Maryland 21225

U.S. Nuclear Corporation
a Division of International Chemical
and Nuclear Corporation
801 North Lake Street
Burbank, California 91503

Louis Ried, Jr.
195 Panwnew Drive
Boulder, Colorado 80303

Security Engineering Co., Inc.
4432 Woodlark Center
Clemen, North Carolina 27012

Notifier Corporation
3700 North 56th Street
Lincoln, Nebraska 68504

Amersham/Searle Corporation
2636 South Clearbrook Drive
Arlington Heights, Illinois 60005

Health Physics Associates Ltd.
2356 Skokie Valley Road
Highland Park, Illinois 60035

Searle/Anaitic
2000 Nuclear Drive
Des Plaines, Illinois 60018

Austin Science Associates, Inc.
5902 West Dee Caves Road
Austin, Texas 78746

Gulf Nuclear Inc.
P.O. Box 5866
Houston, Texas 77058

Mettler Instrument Corporation
Princeton Road
Heightstown, New Jersey 08542

C-E Invalco
1350 Lewisville Road
Tulsa, Oklahoma 74145

Sargent-Welch Scientific Company
7300 Linder Avenue
Skokie, Illinois 60076

Radiation Materials Co., Inc.
124 Calvary Street
Waltham, Massachusetts 02154

Source Production & Equipment Company
625 Oxley Street
Kenner, Louisiana 70062

Stock Equipment Company
731 Hanna Building
Cleveland, Ohio 44115

Dr. J.Goldstein
Medi-Physics
5801 Christie Ave.
Emoryville, Ca. 94708

Parckard Instrument, Co., Inc.
2200 Warrenville Road
Downers Grove, Illinois 60515

Tracor, Inc.
7500 Traco Lane
Austin, Texas 78721

Texas Nuclear Corporation
P.O. Box 9267
Austin, Texas 78766

Gearhart-Owen Industries, Inc.
1100 Everman Road
Fort Worth, Texas 76101

Gammatron, Inc.
Nuclear Sources and Services
5707 Etheridge Road
Houston, Texas 77017

Troxler Electronic Laboratories, Inc.
P.O. Box 12057
Cornwallis Road
Research Triangle Park, North Carolina
27709

Abbott Laboratories
1400 Sheridan Road
North Chicago, Illinois 60064

Nuclear Research & Development Co.
Nuclear Instruments and Accessories
P.O. Box 1261
Berkley, Michigan 48072

American Nuclear Products
1232 East Commercial
Springfield, Missouri 65803

Scientific Products
1430 Waukegan Road
McGaw Park, Illinois 60085

Princeton Gamma-Tech, Inc.
Box 641
Princeton, New Jersey 08540

Internetics, Inc.
2275 Southwest Temple
Salt Lake City, Utah 84119

Dynamics, Inc.
2125 Ivy Square
Charlottesville, Virginia 22903

Radium Chemical Company
161 East 42nd Street
New York, New York 10017

Ranger Electronics Corporation
P.O. Box 863
Alva, Oklahoma 73717

Seaman Nuclear Corporation
3846 West Wisconsin Avenue
Milwaukee, Wisconsin 53208

APPENDIX F

Analysis of Public Comments on NUREG-0301

APPENDIX F

ANALYSIS OF PUBLIC COMMENTS ON NUREG-0301

In July, 1977, NUREG-0301, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials" was published. A Federal Register notice requesting public review and comment was printed July 21, 1977. Two hundred persons in State and Federal Government, private industry and other sectors were contacted individually. In response, the following correspondence was received (PR-Misc [42 FR 37458]):

Respondent	Abbreviation	Docket No.
Robert Alan Parker	RAP	1
Virginia Department of Health	Va.	2
Campbell Pacific Nuclear	CPN	3
Oregon Department of Human Resources	Ore.	4
Rio Algom Corporation	RAC	5
U.S. Department of Interior Mining Enforcement & Safety Administration	MESA	6
U.S. General Services Administration	GSA	7
U.S. Environmental Protection Agency	EPA	8
Amersham Corporation	AC	9
U.S. Department of Health, Education and Welfare, Center for Disease Control, National Institute for Occupational Health & Safety	CDC-NIOSH	10
American College of Nuclear Physicians	ACNP	11
Arkansas Department of Health	Ark.	12
New England Nuclear	NEN	13

Respondent	Abbreviation	Docket No.
National Council on Radiation Protection and Measurements	NCRP	14
U.S. Department of Health, Education, & Welfare, Food & Drug Administration	FDA	15
Westinghouse Electric Corporation	W	16
New York State Energy Office	NY	17
American Iron & Steel Institute	AISI	18
U.S. Department of Commerce, National Bureau of Standards	NBS	19
Dielman Consultants, Inc.	DCI	20
University of Minnesota	UMinn	*
Colorado Department of Health (2 letters)	Colo.	*
Southern Interstate Nuclear Board	SINB	*
Illinois Department of Public Health	Ill.	*
U.S. Department of Energy	DOE	**

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* Comments were not addressed to Secretary of Commission, Attention: Docketing and Service Branch. Records Facility Branch, ADM were furnished copies and requested to handle as responses to PR-Misc. (42 FR 37458).

** Comment received two months after expiration of comment period. Copy was furnished to the NRC PDR.

Detailed analysis of the comments follow below. A summary of the comments appears in Table F-1. The commentor's abbreviations in parenthesis refer to responses which best represent the particular comment.

Support of the task force recommendation was expressed by 84% (21 of 25) of the comments received. Eight (8) expressed unreserved support (NBS, NY). Thirteen (13) others expressed varying degrees of qualification of the support. The most frequently expressed qualification concerned the need to provide NRC with adequate staff to handle the regulation of NARM (AC). Two respondents opposed the recommendation (EPA, W). Two respondents provided comments but took no position (CDC-NIOSH, UMinn).

State Comments

Six (6) states commented. All supported the recommendation but two states raised questions which concerned how NRC would recognize state programs (Va.and N.Y.) and the NRC staffing required to handle NARM (Ill.). One state noted minor technical errors in the report (Colo.).

Federal Agency Comments

Twenty-two (22) Federal Agencies, other than NRC, were identified in the report as having possible regulatory interests in NARM and were contacted by letter from the task force chairman (see Appendix D). Seven (7) responded. GSA and NBS fully supported the recommendation. NBS noted that the recommendation was identical to NBS's comments to OMB regarding EPA's proposed bill to regulate naturally occurring radioactive materials (see below, concerning EPA's comments).

The Department of Interior's Mining and Enforcement and Safety Administration (MESA) endorsed the recommendation but requested clarification of NRC regulatory role over mines. This need for clarification was expressed by CDC-NIOSH.

FDA stated that, "As a long range goal, it appears logical to include all radioactive material under the authority of one agency with the intent of having one national, uniformly applied program to control user radiation safety and to set performance standards

for products and devices, regardless of the origin of the radioactive material." FDA also stated, "As a long term goal, Federal regulatory control should be sought for imported NARM items, exempt NARM items and all NARM items manufactured and used in non-licensing States." FDA, however, believes a voluntary FDA-State cooperative program currently under development should be completed and time given to implement and evaluate this collaborative approach.* (FDA's letter is attached to this Appendix as Attachment 1.)

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* The FDA-State program involves a voluntary, cooperative effort by the states to regulate NARM. The Suggested State Regulations for Radiation Protection provide the regulatory model. "NARM Guides" have been developed which provide regulatory guidance to the states, and also provide assistance to manufacturers, assemblers and distributors with regard to radiation safety aspects for NARM sources and products. These documents have been developed as a result of cooperative efforts involving the states, FDA, NRC, and EPA. NRC has concurred in the Suggested State Regulations (they provide the basis for developing Agreement State regulations) and in the NARM guides (these are comparable to existing NRC regulatory practices for by-product, source and special nuclear materials).

This program has been an invaluable interim asset to those States which have chosen to establish regulatory, and in particular licensing, programs for NARM. The Bureau of Radiological Health and the participating States deserve commendation for undertaking and supporting this program. Despite some significant inherent deficiencies, as noted below, it has served as a technical information clearing house on NARM sources. Much of the work already accomplished can be directly applied in a more formalized regulatory program.

The system, however, already is subject to weakness that prevents it from providing an adequate regulatory basis for controlling NARM. NUREG-0301 reported that seven states have neither a licensing nor registration program for NARM and no comments were received differing with this view (including from these 7 states). There are no incentives identified in the FDA program which would cause development of even minimal regulatory programs in these states or to maintain adequate programs in other states. One State - New York - because of budget constraints for several years has not evaluated NARM sealed sources and devices. New York does perform such evaluations for radioactive materials covered by the Section 274 Agreement with the State in fulfillment of that Agreement. (NARM is not covered by current Section 274 Agreements.) The absence of such evaluations by New York is significant. Radium Chemical Co., New York, is a major U.S. supplier of sealed radium and radon sources for medical, industrial and research users and still supplies radium luminous compounds. (Footnote continues on next page).

The Department of Energy (DOE) supported the recommendation, noting that such action would lead to a single regulatory agency responsible for all radioactive material and this would be consistent with the International Atomic Energy Agency (IAEA) model regulatory code developed in conjunction with the World Health Organization (WHO) which treats all radioactive materials. DOE also noted the need for NRC to properly plan for disposal of radium wastes.

One Federal Agency did not take a position on the recommendation (CDC-NIOSH).

The U. S. Environmental Protection Agency opposed the recommendation (EPA). EPA stated, "...we believe there is available within EPA the necessary authorities to provide radiation protection from naturally-occurring radionuclides. Currently we are developing an overall plan and rationale to draw those authorities administered by EPA into a consistent program of uniform regulations which preclude the need for further regulation." With respect to uranium mill tailings, EPA noted it was meeting with NRC to assure adequate public health protection with proper regard to the roles of each Agency and that the recommendation, as applied to mill tailings, would duplicate EPA authorities under the Resource Conservation and Recovery Act and Clean Air Act Amendments. EPA also expressed the view that Congress has purposefully intended that NRC's mission be limited to "fission related facilities, materials and by-products." (EPA's letter is attached to this Appendix as Attachment 2.)**

The staff noted that the voluntary FDA-State program does not address two areas that need Federal - not State - action for effective control: Importing of NARM and surplusing and other supplying of NARM by Federal Agencies.

Lastly, the staff does not believe that effective control over NARM used in consumer products will be obtained through a voluntary Federal-State program having the deficiencies just cited.

**As noted in NUREG-0301, EPA proposed a bill to directly regulate naturally occurring radioactive materials. The EPA comment contained no reference to its proposed bill, and, on the surface, stands in apparent contradiction to EPA's action early in 1977 when it proposed legislation to provide additional authority for itself over naturally occurring radioactive materials. The EPA comment also did not specifically speak to accelerator-produced radioactive materials.

The staff examined the statutes identified in the EPA comments and has concluded that EPA's statement that, "Existing law... provides EPA with a variety of authorities to control NARM in environmental media, wastes, effluents, emissions, and as a toxic material in products..." is essentially correct. (Summaries of the staff review of these statutes are attached to this Appendix as Attachment 3.)

The task force, in its report, did not find that these various authorities had been effectively implemented. This view is consistent with a General Accounting Office report concerning EPA's radiation protection program, dated January 20, 1978. * (The GAO summary of its report is attached as Attachment 4.)

Even if EPA were effectively implementing its authorities -- and it is not -- the task force pointed out in its report that the regulation of some radioactive materials under the Atomic Energy Act, as amended, and other materials under other statutes is a division of Federal regulatory authority that is unrelated to hazard. Rather, it is the result of Congressional concerns in 1946 and the immediately following years to narrowly focus on the perils of the atomic bomb and the problems related to control of material associated with the fission process. NARM was excluded from the Atomic Energy Act. In the succeeding years, a need for regulating NARM in various activities became recognized. Since the Atomic Energy Act excluded NARM, authority for Federal regulation of these materials has been included in various legislation affecting other Federal agencies including EPA.

It can be reasonably argued that such division of authority, in addition to being subject to unequal levels of effort to implement them, also entail inefficiencies that result from the need to create and maintain qualified staff and programs in each of the affected agencies.

Thus, the question of seeking authority for NRC to regulate NARM, requires not only consideration of whether there is existing, adequate Federal authority to regulate these materials, but also consideration of the questions of whether or not other Federal agencies are adequately carrying out their existing responsibilities in this area and what Federal approach represents the best in economies and efficiency.

Assuming this to be an appropriate framework in which to analyze the EPA comment, simple existence of regulatory authorities for other agencies is not sufficient reason to dismiss further consideration of the task force recommendation.

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* Contrary to the recommendation in this paper, the GAO report, which focuses on EPA's responsibilities, recommended that this deficiency be remedied by strengthening EPA's authority and resources for controlling environmental exposure to radiation.

Weight must also be given to the fact that States did not make a general request of the Federal Government to act, nor did the States approach any other Federal agency. Rather, this agency was specifically named and asked to extend its authority over NARM.

Logically, the NRC is the most appropriate Federal agency to regulate NARM since it presently regulates radioactive materials other than NARM (which present similar radiation protection problems) and already has in place the organizational structure, regulations and licensing and inspection procedures necessary to conduct a regulatory program over NARM. In addition, it has the authority to transfer its regulatory responsibilities to the States when it finds the States have established regulatory programs that are adequate and compatible with those of the NRC.

No responses were received from the other 15 Federal agencies, including the Occupational Safety and Health Administration and the Consumer Product Safety Commission.

NARM Manufacturers and Distributors

Seventy-two (72) manufacturers and distributors of NARM were contacted and asked to comment on NUREG-0301 (see Appendix E). Most of these were identified from a reference manual of NARM sources and devices maintained by FDA's Bureau of Radiological Health.*

Three (3) provided comments and all supported the recommendation. One comment stated, "There has long been a program of sales pressure on consumers to buy the radium devices because it is '...so safe it doesn't even require a license'... Such equipment was, in fact, usually higher in external radiation than comparable Byproduct Material devices and with questionable internal safety features." (CPN).

Other Industrial

Three (3) responses were received from other members of the industrial sector. Two (2) supported the recommendation including a uranium mine and mill operator (RAC).

One respondent opposed the recommendation (W) stating, in part, "In the absence of regulation, conscientious users will remain conscientious; despite the presence of regulations, careless users will continue to find ways to cause problems... We question whether any small incremental improvements in the control of NARM brought about by NRC regulation will offset the costs of instituting across-the-board regulatory machinery in one-half of the nation."

* Uranium mine and mill operators were not included.

Professional Societies

One professional society responded and concurred with the recommendation (ACNP).

Other

NCRP supported the recommendation to the extent that it applied to accelerator-produced radioactive materials but withheld endorsement as it applied to naturally-occurring radioactive materials. NCRP felt additional clarification of roles of the different regulatory agencies in regulating these materials was needed.

The Southern Interstate Nuclear Board (SINB) and the American Iron and Steel Institute (AISI) expressed support.

Support was expressed by a private citizen (RAP).

Comments were received from one respondent concerning radium, uranium and thorium-230 in coal and requesting sponsorship of studies in this area (UMinn). No views were expressed on the recommendation. (NMSS has sent a reply referring his request to EPA and OSHA.)

Table F-1

Summary of
Analysis of Public Comments on NUREG-0301

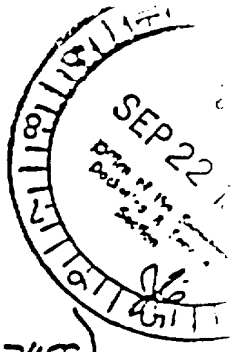
Recommendation that NRC Seek Regulatory
Authority over NARM

Respondent	No. Responses	Full Agreement	Qualified Support or Agreement w/Comment	Disagree	No Position
Federal Agencies	7	2	3	1	1
State Agencies	6	3	3	0	0
NARM Manufacturers & Distributors	3	1	2	0	0
Other Industrial	3	1	1	1	0
Professional Society	1	0	1	0	0
NCRP	1	0	1	0	0
Other	4	1	2	0	1
Totals	25	8	13	2	2
			21		

APPENDIX 1

Attachment 1

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857



Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

(15) PROPOSED RULE FR-Misc (42FR37458)

Attention: Docketing and Service Branch

Gentlemen:

In response to the Federal Register notice of July 21, 1977 (42 FR 37458), we offer our comments on the report, "Regulation of Naturally Occurring and Accelerator-Produced Radioactive Materials--A Task Force Review."

In April 1977, our Bureau of Radiological Health (BRH) commented on an earlier draft of this report which did not include the conclusions and recommendation of the Executive Summary contained on pages 3-4 of the final report. Therefore, we have limited our response mainly to general comments because our specific comments have already been considered by the Task Force.

As a long-range goal, it appears logical to include all radioactive material under the authority of one agency with the intent of having one national, uniformly applied program to control user radiation safety and to set performance standards for products and devices, regardless of the origin of the radioactive material.

In pursuing the goal of obtaining Federal legislative authority to regulate naturally occurring and accelerator-produced radioactive materials, it is suggested that consideration be given to the following:

1. Upon the recommendation of Workshop No. 7 of the Seventh Annual National Conference on Radiation Control in 1975, the Executive Committee of the conference appointed Task Force No. 1:

   "To develop the criteria needed to perform an adequate evaluation of devices, sealed sources, foils, dials, and matrices which contain naturally occurring or accelerator-produced radioactive material (NARM) and factors regarding their interstate distribution. By means of these criteria to provide a mechanism for State-Federal control of the manufacture and distribution of subject sources and products not covered under the Atomic Energy Act."

   This Task Force is composed of State personnel representing the Conference of Radiation Control Program Directors (CRCPD) and representatives of the Nuclear Regulatory Commission, the Environmental Protection Agency, and the Bureau of Radiological Health, FDA. The Task Force has met several times over the past two years and has developed a set of NARM Guides as part of a nationwide system for the uniform evaluation and control of products containing NARM (which includes the Radioactive Materials Reference Manual and the Suggested State Regulations for Control of [illegible]

cooperative efforts of the States and the Federal Government. The NARM Guides will also provide assistance to manufacturers, assemblers, and distributors regarding radiation safety aspects for NARM sources and products. Uniform application of the NARM Guides by radiation control agencies will serve to promote radiological safety in the manufacture, assembly, and distribution of NARM sources and products.

It is important that this voluntary NARM program which has received a great many man-hours of effort in its development by members of the CRCPD, NRC, EPA, and ERH be supported by the participating groups and given sufficient opportunity to function now that work on the NARM Guides has been completed. The NARM Guides were not available in 1974 when the Agreement States recommended Federal legislation governing naturally occurring and accelerator-produced radioactive material. The States through the CRCPD have now indicated their support of the NARM Guide program.

As a long-term goal, Federal regulatory control should be sought for imported NARM items, exempt NARM items, and all NARM items manufactured and used in non-licensing States. However, the process of seeking legislative authority for Federal control of NARM at this time should not detract from continued development of the voluntary State-Federal cooperative NARM program. The voluntary NARM program should be compatible, to the extent possible, with the Federal NARM control program which is to be developed in the future. Therefore, supporting and strengthening the voluntary NARM program at this time should contribute toward development of the Federal NARM control program as a long-range goal.

2. Although the Task Force report reflects considerable effort and provides a useful overview of the current status of agency responsibilities and limitations in the control of NARM material, it appears that there is a lack of sufficient current data to justify and serve as the basis for requiring a new initiative of Federal legislative authority to establish a regulatory control program. Much of the data in NUREG-0301 was taken from an FDA report (FDA 72-8001) published in 1971 and based on a study now almost ten years old. Considerable portions of this latter report were based on initial surveys of users made by State agencies during the 1950's and 1960's when State radiation control programs were just developing.

   The report points out that various Federal Agencies have authority for control over various aspects of the use of NARM and correctly notes that these agencies have not instituted specific controls. The report fails to note, however, that when specific actions were

proposed at the Federal level, it was not possible to show that the use of NARM represents sufficient hazard to the public to warrant action when compared to other agency priorities.

The Task Force report provides a basis for a further study on the comparative effectiveness and costs of a Federal licensing program versus a voluntary State-Federal program to assure the health and safety of the public in the use of the radioactive materials. The Task Force report provides no data on actual radiation hazards or injuries due to NARM, by-product, source, or special nuclear materials upon which to make a comparative hazard analysis. A further study would evaluate the effectiveness of the voluntary Federal-State NARM program. The Food and Drug Administration would be interested in participating in such a study, which should be accomplished with the support of all interested Federal Agencies as well as the CRCPD.

3. As indicated in the report, the FDA has authority to regulate medical radiation sources under the Medical Device Amendments of 1976 (Public Law 94-295, 90 Stat 539-583) of the Federal Food, Drug, and Cosmetic Act. This authority would include medical radiation sources containing NARM. BRH is the lead Bureau in FDA dealing with manufacturers of the following types of medical devices: (a) all medical devices which are electronic products subject to the Radiation Control for Health and Safety Act (x-ray machines, medical lasers, microwave and acoustic devices); (b) medical devices other than electronic devices subject to the Radiation Control for Health and Safety Act of 1968 but which emit ionizing radiation essential to their intended function (cobalt-60, teletherapy, brachytherapy sources, etc.); and (c) accessories or components of products falling under categories (a) or (b) which may influence the quantity, quality, or direction of the radiation emitted or produced (x-ray film, screens, image receptors, film processors, nuclear medicine scanners, etc.). We believe the second paragraph on page 30 of the NRC Task Force report may give the impression that BRH is only involved with voluntary recommendations in this area, whereas they are responsible for a regulatory program under the authority of the Medical Device Amendments for the types of medical devices indicated above.

Under (1) of Conclusions on page 43 of the report, the impression may be given that FDA does not have authority for pre-market approval of NARM radioactive medical sources under the Medical Device Amendments of 1976. The statement should be clarified by deleting the following sentence: "There is no Federal program requiring pre-market approval of NARM radioactive medical sources or requiring the sources to conform with specified manufacturing and quality control standards." The classification of medical devices is actively under development by FDA as is the promulgation of regulations on "good manufacturing prac-

tice." The FDA classification program involves a systematic examination of the risk of injury and will provide a reasonable basis for the decision on requiring Federal pre-market approval.

At the top of page 30 discussing regulatory functions of the Department of Health, Education, and Welfare, the impression is given that only the regulations of Agreement State programs may be exempted from preemption at this time. The proposed rule regarding exemption from preemption under Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) indicates that State or local requirements applicable to medical devices would be preempted only when a corresponding FDA requirement becomes applicable to a particular device by operation of the Act (see 42 FR 30383; June 14, 1977). Therefore, at the present time, the regulations of non-agreement States would not be preempted because FDA has not imposed any corresponding requirements under the Federal Food, Drug, and Cosmetic Act.

In summary, we would like to stress the NARM program being developed in cooperation with the CRCPD and the Federal Agencies--NRC, FDA, and EPA. The States through the CRCPD have indicated their support of the NARM Guide program. The NARM Guides were not developed in 1974 when the Agreement States recommended Federal legislation governing naturally occurring and accelerator-produced radioactive material. However, developmental work has now been completed on this project, and time is needed to evaluate the effectiveness of this collaborative approach. We would be interested in participating in such an evaluation which should provide a firm basis for determining whether Federal legislation may be needed in the future. This should be accomplished with the support of all interested Federal Agencies as well as the CRCPD.

Sincerely yours,

Joseph P. Hile

Joseph P. Hile
Associate Commissioner for Compliance

APPENDIX F, Attachment 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

18 AUG 1977

Honorable Samuel J. Chilk
Secretary of the Commission
Nuclear Regulatory Commission
1717 H Street, NW
Washington, D.C. 20555

Dear Mr. Chilk:

The Environmental Protection Agency has reviewed the Task Force Report on the Regulation of Naturally-Occurring and Accelerator-Produced Radioactive Materials which was provided to us for comment by Mr. D.A. Nussbaumer. We have also noted the publication (42 F.R. 37854) of a request for comments on the recommendations of the Task Force; this letter is in response to both of these requests. The Task Force has made a commendable effort to summarize many of the issues related to the control of naturally-occurring and accelerator-produced radioactive materials. However, we do not believe the recommendation that the NRC seek additional new legislative authority to regulate naturally-occurring and accelerator-produced radioactive materials (NARM) is warranted, based upon the information presented in the report.

Creation of such additional radiation control authority in the Nuclear Regulatory Commission would imply that the NRC's mission is the general protection of public health from radiation exposure per se, rather than its more limited role as regulator of atomic energy related facilities, materials, and by-products. On pages 37 through 42 of the report, it is noted that in 1946, 1954, 1959, and again in 1975, when Congress significantly modified legislation affecting NRC (or its predecessor AEC), it consistently limited the Agency's authority to atomic fission related facilities, materials, and by-products. Clearly, Congress could have permitted the NRC to become the Federal agency with total jurisdiction over the control of all radioactive materials and radiation exposure if it so desired. Rather, Congress has chosen to assign the various responsibilities for the control of radiation, and radioactive materials other than source, by-product, and special nuclear materials, to agencies such as the Consumer Product Safety and Health Administration, the Department of Health, Education, and Welfare, the Occupational Safety and Health Administration, the Mining Enforcement and Safety Administration, and the Environmental Protection Agency. Such legislation has generally dealt with radiation as one of several pollutants or hazards to be controlled under the general functional responsibilities of these respective agencies.

8-25-77

[illegible] to include [illegible] by the Atomic Energy Act. We believe that such a definition [illegible] would be inappropriate to [illegible] and other [illegible] products of the fission process.

The reason expressed by the Task Force for their recommendation is "that these materials (naturally-occurring and accelerator-produced radioactive materials) present significant radiation exposure potential, and present controls are fragmentary and non-uniform at both the State and Federal level." We believe that the recommendations in the report would not bring about appropriate control over major sources of exposure to these materials, and would act to increase fragmentation of Federal agency responsibilities related to these sources of exposure. For example, the report states that "the recommendations do not cover activities where NARM is encountered in-situ, is incidentally present in mineral industry activities outside of the fuel cycle, or is an incidental contaminant in consumer products." However, work by this Agency, some of which was discussed in the Task Force Report, suggests that these exposure situations are considerably more significant to public health than the NARM sources which would be encompassed by the proposed legislative changes.

Existing law, including the Resource Recovery and Conservation Act, the Toxic Substances Control Act, the Federal Water Pollution Control Act, the Clean Air Act with 1977 amendments, and the Marine Protection and Sanctuaries Act, provides EPA with a variety of authorities to control NARM in environmental media, wastes, effluents, emissions, and as a toxic material in products. As recognized in the report, additional authorities exist in the authorizing legislation for the Consumer Product Commission, the Food and Drug Administration, and the Occupational Safety and Health Administration for regulating NARM in consumer products, in medical devices, and as a hazard to workers. If there are any deficiencies in regulation of these items, this should be corrected through properly coordinated increased use of these authorities, not through additions to the already voluminous authority to deal with radiation hazards. With the recently passed legislation cited above and the existing Federal Water Pollution Control Act, we believe there is available within EPA the necessary authorities to provide radiation protection from naturally-occurring radionuclides. Currently we are developing an overall plan and rationale to draw those authorities administered by EPA into a consistent program of uniform regulations which precludes the need for further legislation. We would welcome the participation of NRC in this effort.

With respect to uranium mill tailings, EPA has held initial meetings with staff members of NRC to insure that EPA's newly enacted responsibility to regulate radioactive NARM wastes is exercised effectively, so that together we can provide adequate public health protection from this

[illegible] purpose set forth by the Atomic [illegible] Act of 1974. In [illegible], the proposed Task Force recommendations, as they apply to [illegible] mill tailings, would duplicate responsibilities now assigned to the Environmental Protection Agency under the Resource Conservation and Recovery Act, and the Clean Air Act Amendments.

In summary, we believe that extension of NRC's authority to NARM is outside the purpose set forth for the Commission by the Atomic Energy Act and the Energy Reorganization Act of 1974, and would represent an inefficient use of resources and duplication of existing Federal responsibilities. Therefore, we recommend that the Commission not seek the additional authority recommended by the Task Force. We would welcome the opportunity to meet with your staff to discuss these mutual concerns, and to explore further the alternatives and needs for improved control of NARM materials.

Thank you for providing us the opportunity to comment on these proposals.

Sincerely yours,

W. D. Rowe, Ph.D.
Deputy Assistant Administrator
for Radiation Programs (AW-458)

STATUTE SUMMARIES

I. Toxic Substances Control Act

Public Law 94-469, October 11, 1976, 90 Stat. 2003, 15 U.S.C. § 2601 et seq.

The purpose of the Toxic Substances Control Act is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances and mixtures. The Act is designed to fill a number of regulatory gaps which currently exist, such as pre-market scrutiny of chemical substances prior to first manufacture, direct regulation of chemical substances, and consideration of all risks associated with chemical substances.

The Act gives EPA broad authority to (1) require the development by manufacturers and processors of adequate data with respect to the effect on health and environment of chemical substances which they manufacture or process, (2) regulate hazardous chemical substances and mixtures, namely those with respect to which the Administrator has found that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal thereof presents or will present an unreasonable risk of injury to health or the environment, and (3) to carefully control, through court-ordered seizure or other relief when necessary, chemical substances or mixtures or any article containing such substances or mixtures which present imminent hazards.

The term "chemical substance" is defined in the Act as "any organic or inorganic substance of a particular molecular identity, including-- (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical." The term "chemical substance" does not include mixtures which are separately defined, in part, as "any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; ..." Although source, byproduct and special nuclear material are expressly excluded from the definition of "chemical substance", NARM clearly falls within the scope of the definition. Thus, EPA has authority to regulate NARM in accordance with the provisions of the Toxic Substances Control Act.

II. Resource Conservation and Recovery Act of 1976
Public Law 94-580, October 21, 1976, 90 Stat. 2795, 42 U.S.C. 6901 et seq.

The objectives of this Act, which is administered by EPA and amended the Solid Waste Disposal Act are to (1) assist counties, cities and States in the solution of the discarded materials problem; (2) provide nationwide protection against the dangers of improper hazardous waste disposal; and (3) spark a cooperative effort among Federal, State and local governments and private enterprise to recover valuable materials and energy from solid waste. The Act defines "solid waste" as

> "...any garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other discarded material, including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agriculture operations, and from community activities, but does not include solid or dissolved material in domestic sewage, or solid or dissolved materials in irrigation return flows or industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended (86 Stat. 880), or source, special nuclear, or byproduct material as defined by the Atomic Energy Act of 1954, as amended (68 Stat. 923)."

Hazardous waste is defined as:

> "...a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may--
>
> "(A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or
>
> "(B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."

Subject to certain exceptions, any NARM contained in discarded material resulting from industrial, commercial, mining, and agriculture operations and from community activities would be considered solid waste within the meaning of the Act. However, the statutory definition of solid waste would not include NARM found in solid or dissolved form in domestic sewage or in irrigation return flows or NARM found

in industrial discharges which are point sources subject to permits under section 402 of the Federal Water Pollution Control Act, as amended. Any NARM found to be solid waste within the meaning of the Act, would in most instances, in our opinion, also meet the statutory definition of hazardous waste.

Under the provisions of the Resource Conservation and Recovery Act, EPA has jurisdiction over uranium mill tailings because solid waste is defined to include discarded material from mining activity and uranium mill tailings do not qualify as source, byproduct or special nuclear material.

EPA's regulatory responsibilities with respect to hazardous wastes are set out in Subtitle C. of the Resource Conservation and Recovery Act. Any NARM determined to be hazardous waste would be subject to regulation by EPA pursuant to this authority.

The relationship between the Resource Conservation and Recovery Act and other federal laws is specifically provided for in section 1006 of the Act which states in part:

> "Nothing in this Act shall be construed to apply to ... any activity or substance which is subject to the Federal Water Pollution Control Act, ... the Safe Drinking Water Act, ... the Marine Protection, Research and Sanctuaries Act of 1972, ... or the Atomic Energy Act of 1954 ... except to the extent that such application (or regulation) is not inconsistent with the requirements of such Acts...."
>
> "The Administrator shall integrate all provisions of this Act for purposes of administration and enforcement and shall avoid duplication, to the maximum extent practicable, with the appropriate provisions of the Clean Air Act, ... the Federal Water Pollution Control Act, ... the Federal Insecticide, Fungicide, and Rodenticide Act, ... the Safe Drinking Water Act, ... the Marine Protection, Research and Sanctuaries Act of 1972 ... and such other Acts of Congress as grant regulatory authority to the Administrator. Such integration shall be effected only to the extent that it can be done in a manner consistent with the goals and policies expressed in this Act and in the other acts referred to in this subsection."

Section 6003 of the Act directs all Federal agencies having functions relating to solid waste or hazardous waste to cooperate with the EPA Administrator in carrying out his functions under the Act to the maximum extent permitted by law.

III. Federal Water Pollution Control Act, as amended
33 U.S.C. 1151 et seq.

The objective of the Federal Water Pollution Control Act (FWPCA) is to restore and maintain the chemical, physical and biological integrity of the Nation's waters. To this end, the Act establishes national policies which include prohibition of discharges of toxic pollutants in toxic amounts, and sets national goals which include elimination by 1985 of discharges of pollutants into navigable waters. The Administrator of EPA has broad authority under the Act to achieve these goals and objectives, including, among other things, authority to establish effluent limitations for point sources, establish pre-treatment effluent standards, prohibit or establish effluent standards for discharges of toxic pollutants, prescribe water quality criteria, review and approve or disapprove state water quality standards and implementation plans, issue permits for the discharge of pollutants, and seek judicial relief upon receipt of evidence that a pollution source or combination of sources presents an imminent and substantial endangerment to the health or welfare of persons.

Section 511(c) of the Act specifically provides that nothing in the National Environmental Policy Act of 1969 shall be deemed to authorize any Federal agency to review any effluent limitation or other requirement established pursuant to the FWPCA or the adequacy of any certification under section 401 of the Act, or to impose, as a condition of any license or permit, any effluent limitation other than one established pursuant to the FWPCA.

The term "pollutant" is defined in the Act to mean, among other things, "solid waste, ... chemical wastes, ... radioactive materials, heat, ... rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water...." The term "toxic pollutant" means

> "those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring."

On June 1, 1976, in Train v. Colorado Public Interest Research Group, Inc., 426 U.S. 1, the U.S. Supreme Court held that source, byproduct and special nuclear materials regulated by NRC are not pollutants within the meaning of the FWPCA. NARM, on the other hand, is clearly a pollutant within the meaning of the Act, and could, in many instances, depending on the facts, be found to be a toxic pollutant within the meaning of the Act.

IV. Clean Air Act with 1977 Amendments

SECY-77-448A, October 31, 1977 contains a general account of the regulatory framework of the Clean Air Act and a detailed analysis of the Clean Air Act Amendments of 1977. Although this paper is primarily concerned with the impact of the 1977 amendments on facilities and materials regulated by NRC, the presentation makes it quite clear that NARM which is emitted into or otherwise enters the ambient air is an air pollutant within the meaning of the Act and as such fully subject to the regulatory provisions of the Act, including the provisions for the control of hazardous air pollutants.

(See detailed Analysis of 1977 Clean Air Act Amendments attached to SECY-77-448A, especially pp. 1-3, 4-5, 13-14, 26-37.)

V. Marine Protection, Research and Sanctuaries Act of 1972
Public Law 92-532, as amended, October 23, 1972, 86 Stat. 1052, 33 U.S.C.A. § 1401 et seq.

The purpose of Title I of the Act, which is administered by EPA, is to regulate the dumping of all types of materials into ocean waters and to prevent or strictly limit dumping into those waters of any material that would adversely affect human health or welfare, or the marine environment, ecological systems or economic potentialities. Dumping of radiological warfare agents or high-level radioactive waste 1/ is prohibited. Permits are required for dumping other materials.

1/ "High-level radioactive waste" is defined in the Act as

> "the aqueous waste, resulting from the operation of the first cycle solvent extraction system, or equivalent, and the concentrated waste from subsequent extraction cycles, or equivalent, in a facility for reprocessing irradiated reactor fuels, or irradiated fuel from nuclear power reactors."

The term "material" is broadly defined in the Act to mean "matter of any kind or description, including, but not limited to,.... [among other things] solid waste, ... radiological ... warfare agents, radioactive materials, ... and industrial, municipal, agricultural, and other waste;" ...

The term "dumping" is also broadly defined as "a disposition of material." This statutory definition, however, does not mean

> "a disposition of any effluent from any outfall structure to the extent that such disposition is regulated under the provisions of the Federal Water Pollution Control Act, as amended, ... under the provisions of section 13 of the Rivers and Harbors Act of 1899, as amended, ... or under the provisions of the Atomic Energy Act of 1954, as amended ... nor does it mean ... the construction of any fixed structure or artificial island nor the intentional placement of any device in ocean waters or on or in the submerged land beneath such waters, for a purpose other than disposal, when such construction or such placement is otherwise regulated by Federal or State law or occurs pursuant to an authorized Federal or State program ..."

NARM falls squarely within the statutory definition of "material" and would therefore be subject to EPA's regulatory authority under the provisions of this Act.

VI. Occupational Safety and Health Act of 1970
Public Law 91-596, December 29, 1970, 84 Stat. 1590, 29 U.S.C.A. § 651, et seq.

The objective of the Occupational Safety and Health Act of 1970 is to assure so far as possible safe and healthful working conditions for every working man and woman in the Nation. Towards this end, the Act requires each employer to furnish to each of his employees "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." The Act also requires each employer to "comply with occupational safety and health standards promulgated under this Act." The Act places a similar obligation on employees, requiring each employee to "comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct."

The Act prescribes standards and procedures for the development and promulgation of occupational safety and health standards and authorizes the Secretary of Labor, who is responsible for its

administration, "to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce, ..." Section 6(b)(5) 2/ contains guidelines which the Secretary is required to follow in promulgating standards dealing with toxic materials or harmful physical agents. In addition, the Secretary has authority to establish emergency temporary standards if he determines "... (A) that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new hazards, and (B) that such emergency standard is necessary to protect employees from such danger." The Act provides that emergency temporary standards shall take immediate effect upon publication in the Federal Register and shall remain in effect until replaced by a standard promulgated in accordance with the procedures specified in section 6(b) of the Act.

When conditions or practices in a place of employment are so dangerous that they could reasonably be expected to cause death or serious physical harm immediately or before the imminence of such danger can be eliminated through the enforcement procedures otherwise provided by the Act, the Secretary may petition the courts for immediate judicial relief.

Section 4(b)(1) of the Act states:

> "Nothing in this Act shall apply to working conditions of employees with respect to which other Federal agencies and State agencies acting under section 274 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2021), exercise statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health."

2/ Section 6(b)(5) reads as follows:

> "The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired."

Although this provision limits the reach of OSHA so far as source, byproduct and special nuclear materials are concerned, it does not affect the applicability of the Act to NARM.

VII. Consumer Product Safety Act
15 U.S.C.A. §§ 2051-2081.

The purposes of the Consumer Product Safety Act, which is administered by the Consumer Product Safety Commission, are to protect the public against unreasonable risks of injury associated with consumer products, assist consumers in evaluating the comparative safety of consumer products, develop uniform safety standards for consumer products and minimize conflicting State and local regulations, and promote research and investigation into the causes and prevention of product-related deaths, illnesses and injuries. The Act defines "consumer product" as "any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise; ..." Articles which are "not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer, ..." are not "consumer products" within the meaning of the Act. In addition, certain specific items, such as tobacco and tobacco products, motor vehicles or motor vehicle equipment, food, drugs, devices and cosmetics, are expressly excluded from the definition of consumer product.

The Act authorizes the Consumer Product Safety Commission to promulgate consumer product safety standards, and to promulgate rules declaring certain consumer products banned hazardous products. Requirements included in a consumer product safety standard must be reasonably necessary to prevent or reduce an unreasonable risk of injury 3/ associated with the product. These requirements may relate to such matters as product performance, composition, contents, design, construction, finish, packaging, and any warnings or instructions which may be needed. A consumer product which is or will be distributed in commerce may be declared to be a banned hazardous product if the product presents an unreasonable risk of injury and no feasible consumer product safety standard would adequately protect the public from the unreasonable risk of injury associated with the product.

The Commission is authorized to issue orders prohibiting manufacturers, distributors or retailers of consumer products which present a "substantial

3/ "Risk of injury" is defined in the Act as "... a risk of death, personal injury, or serious or frequent illness."

product hazard" from importing such products, from manufacturing or offering such products for sale, or from distributing such products in commerce. The Commission is also authorized to order manufacturers, distributors or retailers to bring the product into conformity with an applicable consumer product safety standard or repair the defect in the product, to replace the product or to refund the purchase price. A "substantial product hazard" exists where the failure of the consumer product to comply with an applicable consumer product safety rule creates a substantial risk of injury to the public, or where the consumer product contains a "defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public."

In the case of an imminently hazardous consumer product, namely a product which presents imminent and unreasonable risk of death, serious illness, or severe personal injury, the Commission is authorized to seek judicial relief by seizure of the product and/or action against the manufacturer, distributor or retailer.

Section 31 of the Consumer Product Safety Act (15 U.S.C.A. § 2080) provides that:

> "The Commission shall have no authority ... to regulate any risk of injury associated with a consumer product if such risk could be eliminated or reduced to a sufficient extent by actions taken under the Occupational Safety and Health Act of 1970; the Atomic Energy Act of 1954; or the Clean Air Act. The Commission shall have no authority ... to regulate any risk of injury associated with electronic product radiation emitted from an electronic product (as such terms are defined by section 263c(1) and (2) of Title 42) if such risk of injury may be subjected to regulation under subpart 3 of part F of title III of the Public Health Service Act."

Except to the extent that regulation is precluded by this provision, consumer products containing NARM would be subject to the jurisdiction of the Consumer Product Safety Commission.

VIII. Nuclear Medicine

The Federal Food, Drug and Cosmetic Act of 1938 (21 U.S.C.A. §§ 301 et seq.) authorized the Food and Drug Administration to regulate the safety of drugs, including radioactive drugs, offered for interstate commerce through control of product labeling. Legislative amendments

in 1962 gave the FDA tighter controls over drug safety and introduced controls over the efficacy of drugs to foreclose the marketing of safe, adequately labeled drugs that do not work. The Federal Food, Drug and Cosmetic Act of 1938, as amended, also authorized the FDA to control the manufacture of drugs, including radioactive drugs. In 1976, Congress enacted the Medical Device Amendments of 1976, (Public Law 94-295, May 28, 1976, 90 Stat. 539-583) which gave the Food and Drug Administration authority to regulate medical devices similar to its authority to regulate the safety and efficacy of drugs. Drugs and medical devices containing NARM would be covered by this authority.

REPORT TO THE CONGRESS

BY THE COMPTROLLER GENERAL OF THE UNITED STATES

The Environmental Protection Agency Needs Congressional Guidance And Support To Guard The Public In A Period Of Radiation Proliferation

A clearer understanding of the Environmental Protection Agency's responsibilites for providing guidance in radiation matters could lead to more efficient protection of the American people and their environment from the hazards of radiation.

This report discusses a need to better define radiation authorities assigned by law to the Agency so that jurisdictional confrontations may be eliminated and staffing and funding limitations may be corrected.

CED-78-27

JANUARY 20, 1978

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-166506

To the President of the Senate and the
Speaker of the House of Representatives

This report discusses a need to define the radiation authorities of the Environmental Protection Agency to eliminate jurisdictional confrontations and correct existing staffing and funding limitations. A clearer understanding of the Environmental Protection Agency's role could lead to a more efficient program to protect the American people and their environment from the hazards of radiation.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

Copies of this report are being sent to the Acting Director, Office of Management and Budget; the Administrator, Environmental Protection Agency; the Chairman, Nuclear Regulatory Commission; the Secretaries of the Departments of Energy; Health, Education, and Welfare; and Labor; and to interested congressional committees, various Members of Congress, and other interested parties.

Comptroller General
of the United States

COMPTROLLER GENERAL'S
REPORT TO THE CONGRESS

THE ENVIRONMENTAL PROTECTION AGENCY NEEDS CONGRESSIONAL GUIDANCE AND SUPPORT TO GUARD THE PUBLIC IN A PERIOD OF RADIATION PROLIFERATION

D I G E S T

Everyone in American society is exposed to some form of radiation daily. Sources include natural environment, dental and medical X-rays, nuclear powerplants, homes built on radioactive landfill, clocks and watches with luminous dials (to a much smaller degree), and some food products. (See pp. 1 to 5.)

The Environmental Protection Agency in 1970 was given unclear authority to protect the American people and their environment from radiation hazards. Its officials agree with GAO that the Agency currently is unable to provide complete protection under its ambiguous authorities and that clarification by the Congress is needed. (See pp. 7 and 36.)

The Agency's radiation programs have been plagued by

--jurisdictional challenges to the Agency's authority,

--staffing and funding reductions,

--an inability to retain competent professionals,

--limited cooperation with other agencies and research groups, and

--low priority placed on radiation protection.

Of all Environmental Protection Agency programs, radiation protection is the least funded. Continual reductions in radiation protection staff and budget, transfers of professionals to other Agency programs, and discussions with Agency officials currently working at the Office of Radiation Programs lead GAO to the conclusion that

the Environmental Protection Agency has not been given enough support in its radiation protection efforts. (See pp. 15 to 19 and 21 to 26.)

This means that (1) the Agency's program for monitoring radiation levels to which the American people currently are exposed is limited and (2) without extensive changes, the Environmental Protection Agency will continue to be limited in its ability to protect public health and the environment from radiation dangers.

The Agency does not know the scope of dangers caused by all current radiation sources and is unable to anticipate future problems adequately. Some data is incomplete and inadequate. It does not have sufficient staff or money to perform necessary research and so it has not fully secured available data or developed new data. It has been unable to issue timely standards and guidance and has been consistently unable to meet its own deadlines for issuing significant reports, standards, and guidelines. (See pp. 29 to 33.)

The Agency received two authorities for providing radiation protection when it was created in 1970. It can

--issue standards for radioactivity in the environment, including general environmental guidelines for particular industries and for radiation doses to the public, and

--provide guidance to Federal agencies affecting all forms of radiation protection in Federal activities. (See pp. 7 to 9.)

To date from these authorities the Agency has issued one standard--currently not enforced--and has issued no new formal guidance to other Federal agencies. (See pp. 11 to 15.)

Much of man's exposure to radiation is from unavoidable natural background sources as compared to manmade sources. It is recognized that improvements in radiation techniques and control could reduce exposure.

As the sources of radiation increase, the health of the general population may be adversely affected. Because genetic effects are involved, radiation exposure affects the lives of future generations.

Many of the materials that emit radiation have the potential to contaminate the environment for years, some for hundreds of thousands of years. After they've been used in the production of weapons, in the manufacture of electricity, etc., these materials become waste which must be disposed of safely without contaminating drinking water, future home sites, food supplies, or the natural environment.

There have been problems in disposing of nuclear waste materials safely. In some instances accidents have occurred, and in others the dangers were not understood until after contamination had already taken place. (See p. 1.)

RADIATION PROTECTION PHILOSOPHY AND STANDARD

Federal policy is based on the axiom that nuclear energy and the medical, agricultural, scientific, and industrial uses of radiation are essential for human advancement. The proliferation of existing applications and the development of new technology mean that the total sources of radiation are increasing and will continue to increase. The Environmental Protection Agency currently sees its radiation responsibility as balancing potential damage to health and the environment against the benefits of radiation use.

When the Agency issued its first standard on January 13, 1977, after 6 years of development and delays, it established a new criteria for exposure to individual members of the public and limited the quantities of long-lived radioactive materials entering the general environment. (See pp. 10 to 11.)

A HISTORY OF PROGRAM REDUCTIONS

Over the years the Environmental Protection Agency has reduced its emphasis on radiation control. In

1972 funding and overall staffing levels were at a high of $8.8 million and 335 positions. The Agency's request for fiscal year 1978 is $4.8 million and 184 positions for radiation abatement and control. As a result, morale in the Agency's radiation program is low and most people interviewed said that there is not adequate staff, data, laboratory support, or research to do an effective job.

In the beginning of the program, all of the Agency's radiation efforts were centralized in its Office of Radiation Programs. This office had the task of developing guidance and standards and monitoring the environment. Agency officials said that funding and staffing for the office has been cut drastically over the years to the point that further reduction will directly affect its mission capabilities. They explained that because the Congress has not mandated specifically that the Agency provide radiation protection, this protection has not received the same priority as other authorized Agency programs. (See pp. 21 to 22.)

AN INADEQUATE MONITORING NETWORK

The Environmental Protection Agency operates the only nationwide network for monitoring levels of radiation in the environment. Officials responsible for development of criteria, guidance, and standards repeatedly emphasized to GAO that the network and individual field measurement studies are limited and do not support the Agency's full informational needs in all areas. Network monitoring officials said that because of program curtailments, periodic population exposure readings result in an estimated 40 percent of American people not being monitored. (See pp. 22 to 23.)

INABILITY TO SET PRIORITIES

In October 1976 the Agency outlined a draft of the Agency's radiation protection strategy. This called for placing priority on radiation problems that pose the greatest threat to public health and the environment. However, officials told

GAO that staff shortages have prevented the Agency from projecting all needed standards and guidance for the future.

In May 1976 the Environmental Protection Agency acknowledged in a published report that " * * * there are radiation sources for which data are either incomplete or not available * * *" and that much of the existing information is of questionable value. For example, medical X-rays contribute to a large, significant dose of radiation, but the Agency does not know how large and significant the dose actually is. Nor does the Agency sufficiently understand the relationships between exposure to some forms of radiation and their consequences in order to issue reliable predictions. More must be learned about the effects of amount and duration of exposure. The Agency admits that it does not know all the radiation sources that may provide a danger to health and the environment nor do measurements exist for many of the sources that have been identified as a potential threat. (See pp. 29 to 30.)

RECOMMENDATIONS TO THE CONGRESS

To overcome the apparent controversies regarding the role of the Environmental Protection Agency in developing standards and Federal guidance for environmental exposure to radiation, the Congress should:

--Define more clearly the Agency's role as the Federal overseer of environmental radiation.

--Outline the scope of radiation dangers to be determined by the Agency.

--Require timely development of necessary standards and guidance and periodic advisement of the Agency's progress in meeting its radiation protection goals.

RECOMMENDATIONS TO THE ADMINISTRATOR

The Administrator of the Environmental Protection Agency should provide his radiation protection program with sufficient support to do its job. Specifically the Administrator should:

--Assign additional staff and resources as available to the Office of Radiation Programs and to the radiation research program.

--Reexamine the environmental monitoring network and develop the capability to provide accurate and complete information on radiation dangers.

--Coordinate Agency research with that performed by others so that appropriate data can be compiled and developed in a timely manner.

--Require that reports on radiation levels in the environment be continued and issued at least annually.

--Develop a comprehensive assessment of the need for standards and guidance such as those required for radioactive air pollutants.

--Develop standards and guidance based on an explicit time and priority determination of the greatest or potential risks.

--Issue Federal guidance and standards based on that timetable. (See p. 35.)

AGENCY COMMENTS

In a December 1977 letter (see app. II) commenting on GAO's proposed report, the Environmental Protection Agency advised that it has planned or started actions on all GAO recommendations. The Agency recognized the problems in operating a national radiation protection program under its authorities and agreed that congressional clarification of its authorities would be valuable. (See p. 36.)

Comments on the proposed report from other Federal agencies are contained in appendixes III to VI. These agencies cite their own radiation protection activities as active, aggressive, and comprehensive efforts even in the absence of Environmental Protection Agency actions. They generally agreed, however, that a need exists for the Congress to mandate a clearer understanding of responsibilities for environmental and public health protection. (See pp. 37.)

APPENDIX G

Information Considered by the Staff Subsequent to NUREG-0301

APPENDIX G

Information Considered by the Staff Subsequent to NUREG-0301

NUREG-0299, Draft Task Force Report on the Agreement States Program. This task force, in the course of its study of the Agreement State Program, reviewed other NRC studies for possible impacts upon Agreement States. It concluded that only the Study of Federal/ State Regulation of Low Level Waste Burial Grounds would have significant impact. Following publication of the draft report, two of the States which provided comments, Kentucky and Colorado, sharply disagreed with this conclusion and identified the NARM task force report as another report which would have significant impact. The Agreement State task force agreed, and further, in its final report (NUREG-0388, SECY-77-621) endorsed the recommendation of the NARM task force that NRC seek regulatory authority over NARM.

SECY-77-303A. The staff is now drafting proposed legislation which would give NRC authority to directly regulate, as licensed material, naturally occurring radioactive materials in Uranium mill tailings in non-Agreement States.* Such legislation would be, in principle, consistent with the task force recommendation and could be folded into proposed legislation giving NRC authority to regulate NARM in other areas.

NARM Guides. Under sponsorship of the Conference of Radiation Control Program Directors, a task force composed of State, FDA, EPA and NRC representatives, has prepared "Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)," FDA Publication FDA-77-8025. These guides provide regulatory assistance to the States and also provide assistance to manufacturers, assemblers and distributors with respect to radiation safety aspects for NARM sources and devices. NRC participated in the development of these guides and they are considered to be comparable with existing NRC regulatory practices for source, by-product and special nuclear materials. As such, they can easily be integrated into the NRC regulatory program if NRC were to assert jurisdiction over NARM.

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* In Agreement States, all radioactive materials, including NARM associated with milling operations and tailings, are regulated by the States.

Iodine-123. NUREG-0301 noted that the availability and use of accelerator-produced radioisotopes has increased rapidly in recent years, especially in nuclear medicine. In August, 1977, FDA published a report, "The Developing Role of Short-Lived Radionuclides in Nuclear Medicine" (FDA Publication FDA-77-8035) which further highlights this observation. Most of the short-lived radioisotopes considered are accelerator-produced and are considered because they provide improved diagnostic information with lower radiation dose. Iodine-123 was used as the model for this report. On October 18, 1977, FDA published a Federal Register notice (p. 55649) concerning FDA's consideration of issuance of voluntary recommendations for the evaluation of diseases of the thyroid gland. The recommendations were developed from the FDA report. It is expected, if implemented, that these recommendations will probably result in significant increases in the use of Iodine-123. The report also discusses other short-lived, accelerator-produced radioisotopes and advocates support of further studies and research concerning their use.

NCRP Report 56. On November 1, 1977, the National Council on Radiation Protection and Measurements (NCRP) published Report No. 56, "Radiation Exposure from Consumer Products and Miscellaneous Sources. The report identifies sources of exposure, numbers of persons in the United States exposed to the source and average annual dose equivalents to the exposed persons and to the population. NCRP classified the sources into two groups. The first involves exposure of many people and relatively large dose equivalents and the second either involves exposure to large numbers of people and relatively small dose equivalents or vice-versa.

In the first category, radioluminous products, tobacco products, building materials and glasses and ceramics were identified. NCRP commented that elimination of some sources including tobacco products and building materials may "require alterations in basic human behavioral patterns and may be difficult to accomplish." NCRP also commented that ..."certain sources or applications serve little or no useful purpose and should be eliminated" and cited the use of radium-226 in luminous compounds as an example.

Mineral Industry Tailings. New information obtained by the State Agreements Program, SP, indicates that some mineral industry tailings may contain naturally occurring radioactive materials at levels comparable to those found in uranium mill tailings. For example, a zirconium extraction process in Oregon has produced tailings containing radium-226 in concentrations of 300 to 1000 picocuries per gram in a soluble, leachable form. Colorado has licensed a waste pile from a fluorospar

operation which contains radium-226 in concentrations of 300 to 400 picocuries per gram. These radium-226 concentrations are of the same magnitude as those encountered in the tailings from uranium mills, i.e., 100 to 1000 picocuries per gram.

The regulation of such industries for the purpose of radiation health and safety does not fit the established NRC role inasmuch as these minerals are not utilized as source material in the nuclear fuel cycle. As noted in the task force report, EPA should provide regulation of radiation hazards from such industry tailings by application of the Resource Conservation and Recovery Act.

APPENDIX H

Evaluation of Options

APPENDIX H

Evaluation of Options

NUREG-0301 Recommendation

The task force recommendation in NUREG-0301 was:

"With respect to new or improved NRC actions, it is recommended that the Commission seek legislative authority to:

"A. License and regulate NARM as follows: (footnote omitted)

"1. In any activity that is part of, or in support of, the nuclear fuel cycle regulated by NRC."

"2. In any activity where: (a) NARM is manufactured (e.g., production of accelerator radioisotopes, the separation of radium and radium daughters, and radon generators); (b) NARM is incorporated into sources or devices subject to licensing; or (c) NARM is used in the same manner as radioactive materials subject to NRC regulation."

"3. In any activity where NARM is introduced into products intended for distribution to persons exempt from licensing."*

"4. In any activity involving the management of NARM wastes which result from licensed activities.

"B. Extend authority under Section 274 of the Atomic Energy Act to relinquish authority to regulate NARM (except control of the distribution of NARM to persons exempt from licensing) to Agreement States and to other States having existing regulatory programs for NARM which are determined to be adequate and to be compatible."

"* It is intended that this include only activities where the introduction of NARM is deliberate and has as a purpose the utilization of its radioactive properties."

Options

The staff evaluated this recommendation in light of the public comments and information subsequent to issuance of NUREG-0301 and identified six options for Commission action:

Option 1: No Action by NRC;

Option 2: NRC support action giving other Federal agencies the authorities and resources necessary to correct the NARM problems;

Option 3: NRC seek partial authority only (e.g., mill tailings);

Option 4: NRC seek partial authority for itself and support action giving other Federal agencies any other necessary authorities and resources;

Option 5: NRC seek the recommended authority; and

Option 6: NRC seek authority over all radioactive materials.

The pros and cons of these options are as follows:

Option 1. NRC takes no action.

Pros

-- Requires no new or additional commitments of NRC fiscal or staff resources.

-- Preserves the present regulatory framework for NRC.

-- Is consistent with past Congressional actions to limit NRC authority to source, byproduct and special nuclear materials.

-- Does not require changes in the Atomic Energy Act, as amended.

-- Is responsive to the views of some that the hazards to the public health and safety from NARM are not sufficient to merit additional Federal action and that current Federal authorities are adequate.

-- Is consistent with the recommendations contained in the GAO report to Congress concerning EPA's responsibilities for radiation protection.

Option 1. NRC takes no action. (continued)

Cons

-- Is unresponsive to the specific requests from the States that NRC seek regulatory authority over NARM.

-- Is unresponsive to the great majority (84%) of the commentors on NUREG-0301 who supported the recommendation. These include NBS, DOE, GSA and all of the States who commented on the report.

-- Ignores the need for clarification of Federal regulation of these materials, especially where NRC has strong interests, i.e., naturally occurring radioactive materials in mill tailings in non-Agreement States.

-- Serves to continue the present fragmented, non-uniform controls over NARM.

-- Is unresponsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- Ignores the indications of unnecessary and possibly excessive radiation exposure of workers and the public from these sources.

-- Ignores the strong likelihood of continued rapid growth of use of some of these materials, including the substitution of these materials for byproduct, source and special nuclear materials.

Option 2. NRC supports action giving other Federal Agencies the authorities and resources necessary to correct the NARM problems.

Pros

-- Is responsive to the conclusion of NUREG-0301 that present regulatory controls over NARM are fragmented and non-uniform.

-- Requires no new routine staff or fiscal commitments by NRC.

-- Does not require changes in the Atomic Energy Act, as amended.

Option 2. (continued)

Pros (continued)

- Is consistent with past Congressional actions to limit NRC authority to source, byproduct and special nuclear materials.
- Preserves the present regulatory framework for NRC.
- Is consistent with the recommendations contained in the GAO report to Congress concerning EPA's responsibilities for radiation protection.

Cons

- Is not responsive to State requests that specifically identified NRC as the Federal Agency to seek this authority.
- Is not responsive to commentors on NUREG-0301 that endorsed NRC as the Federal Agency to seek this authority.
- Serves to continue, and may worsen, the present fragmentation of regulatory control over NARM.
- Ignores NRC's regulatory interests in certain areas, particularly the regulation of mill tailings in non-Agreement States.
- Except for EPA, no other Federal Agency has indicated specific interest in seeking additional regulatory authority over NARM.
- Ignores the advantages of using and building upon existing NRC pools of expertise and regulatory programs.
- Would complicate State relations with the Federal Government. Recognition of adequate State programs would be uncertain and State agreements with additional Federal Agencies may become necessary.
- Is unresponsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

Option 3. NRC seeks partial authority.

Note: Examples of alternatives for this option include:
(a) seeking authority to regulate naturally occurring radioactive materials in mill tailings in non-Agreement States (SECY-77-303A); and
(b) seeking authority to regulate accelerator-produced radioactive material (as recommended by NCRP).

Pros

-- Would serve to accommodate identified needs of NRC for improved regulatory authority in specified areas.

-- Limits the impact of requirements for additional NRC staff and other resources.

-- Would be consistent with staff actions already approved by the Commission (SECY-77-303A).

-- Except for new, limited authorities requested by NRC, would serve to preserve the present regulatory framework for NARM.

Cons

-- Is not fully responsive to the requests of the States that NRC seek regulatory authority over NARM.

-- Is not fully responsive to most of the comments received on NUREG-0301.

-- Will not necessarily clarify Federal regulation of NARM.

-- Is not totally responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- May ignore some sources of unnecessary and possibly excessive radiation exposure of workers and the public.

-- Requires Congressional action.

Option 4. NRC seeks partial authority and supports action giving other Federal Agencies any other necessary authorities and resources.

Pros

-- Is responsive, in principle, to the State requests for additional Federal regulation of NARM.

-- Is responsive, in principle, to the comments supporting the task force recommendation.

-- NRC's involvement in the regulation of NARM would be limited to those areas where NRC has an established interest, e.g., mill tailings in non-Agreement States.

-- Limits the impact of requirements for additional NRC staff and other resources.

-- Would be consistent with staff actions already being undertaken (SECY-77-303A).

-- Is consistent, in principle, with the recommendations contained in the GAO report to Congress concerning EPA's responsibilities for radiation protection.

Cons

-- Is not fully responsive to State requests for Federal regulation of NARM by NRC.

-- Is not fully responsive to most of the comments on NUREG-0301.

-- Serves to continue the present fragmented Federal regulation of NARM.

-- Is not responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- There is no guarantee that other Federal Agencies would seek, desire, or exercise additional authorities over NARM.

-- If other Federal Agencies are not given other necessary authorities, or do not exercise them, some sources of unnecessary and possible excessive radiation exposure of workers and the public may continue.

-- Requires Congressional action.

Option 5. NRC seeks the authority as recommended in NUREG-0301.

Pros

-- Would be responsive to States' requests that NRC seek such authority.

-- Would be responsive to the great majority (84%) of the comments on NUREG-0301.

-- Would serve to clarify Federal regulation of NARM and to make the regulation of these materials more uniform.

-- Would serve to fill regulatory gaps for NARM.

-- Would be responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member countries be responsible for all radioactive materials.

-- Would assure adequate regulation of all radioactive materials regardless of changes in patterns of use or replacement of one radioactive isotope by another for a particular use.

-- Takes advantage of, and builds upon, existing NRC expertise and programs.

-- Provides for recognition of existing, adequate State programs for regulating NARM by folding in the existing Agreement State program.

-- Current voluntary, cooperative FDA-State regulatory programs can easily be integrated into existing NRC and Agreement State programs.

-- Would be responsive to the recommendation of the NRC task force on Agreement State Programs (NUREG-0388, SECY-77-621).

-- Is consistent with NRC staff actions already underway (SECY-77-303A).

Option 5. (continued)

Cons

-- Requires increase in NRC staff and other resources.

-- Is not consistent with Congressional action taken, to date, which has excluded NARM from NRC control.

-- Is not consistent with the views of EPA, with respect to naturally occurring radioactive materials.

-- Is not fully consistent with the views of FDA.

-- Ignores in-situ naturally occurring radioactive materials and naturally occurring radioactive materials occurring as an incidental contamination in mineral industry or consumer products.

-- Requires Congressional action.

Option 6. NRC seek authority over all radioactive materials, including in situ and as incidental contamination present in mineral industry or consumer products.

Pros

-- Would recognize and establish NRC control over any radioactive material regardless of source or origin.

-- Would be more fully responsive to the implicit recommendation of IAEA and WHO that a single regulatory agency in member nations be responsible for all radioactive materials.

-- Would help assure adequate regulation of all radioactive materials regardless of patterns of use or changes in radioisotopes being used.

Cons

-- Such comprehensive authority for NRC was not requested by the States.

-- Only a very small minority of commentors on NUREG-0301 (two) advocated such authority.

Option 6. (continued)

Cons (continued)

-- Would require significant additions to NRC staff and of other resources.

-- Would conflict with EPA's view that there is sufficient, existing authority to regulate naturally occurring radioactive materials.

-- Requires Congressional action.

Decision Criteria

In evaluating the options, the staff considered the pros and cons in light of the following decision criteria:

-- Would the option provide adequate protection of the public health and safety from the hazards of NARM?

-- Would the option assure Congress and the public that a comprehensive, fully coordinated program exists for controlling the hazards from NARM?

-- Does the option provide adequate definition of Federal and State roles?

-- Does the option simplify the regulation of NARM?

-- Is the option responsive to requests made by the States, and other expressions of interest and concern, including comments on NUREG-0301?

-- Is the option consistent with present NRC policies, actions and concerns?

-- Is the option one which keeps to a minimum new expenditures of Federal funds by NRC and does not detract from other, presently authorized NRC activities?

-- Is the option consistent with Presidential, Congressional and Commission policies to be responsive to State interests and to involve the States in activities affecting the interests of their citizens?

Staff Evaluation

It is the staff's view that Option 5, NRC seek the authorities recommended in NUREG-0301, best fits the decision criteria.

APPENDIX I

Estimation of NRC Resources Needed

APPENDIX I

ESTIMATION OF NRC RESOURCES NEEDED

Data available from SP, based upon Agreement State experience, indicates 25% of existing NRC licensees also use NARM. NARM only users constitute about 5% of Agreement State licensees.

Currently, NRC administers about 8,800 licenses. Twenty-five percent (25%) of these, or 2,200 probably also use NARM.

NARM only users in non-Agreement States are estimated to be 5% of 8,800 or 440. In addition, NRC may need to issue licenses authorizing distribution of NARM to persons exempt from licensing and licenses authorizing distribution of medical sources and generally licensed devices. By comparing existing NRC licensing patterns for these categories with present NARM use, another 50 to 60 licenses issued by NRC may be needed. The total of new licenses to be handled by NRC is estimated to be about 500 assuming existing Agreement State programs for NARM will be recognized by NRC.

Based upon Agreement State experience, about one-half of these licenses will be for medical uses, about one-third will be for industrial purposes and the remainder for other purposes. Assuming inspection intervals corresponding to current IE practice:

Type of License	No.	Inspection Interval	Inspections/Year
Medical	250	3 years	83
Industrial	183	3 years	61
Other	67	10 years	7
Totals	500		151

This will require about 2 person-years of professional IE effort.

NMSS experience suggests that their effort to handle 500 new NARM licenses will also require 2 person-years of professional effort.

SD professional effort should not exceed 1 person-year.

The NRC professional effort needed to handle 500 new NARM licenses is expected to be primarily in IE, NMSS and SD and will be about 5 person-years.

The incremental increase in professional effort due to 25% of existing NRC licenses also authorizing NARM is estimated to be another 2 person-years. For many NRC licenses, the use of NARM is limited to check and calibration sources or is substantially the same as the use of byproduct material, e.g., Iodine-123 vs. Iodine-131 in diagnostic nuclear medicine. The impact upon NRC licensing and inspection and enforcement efforts for these users should be quite small. On the other hand, more impact is expected from the regulation of medical licensees who also use radium and radon brachtherapy sources.

The routine total professional effort needed for NRC regulation of NARM as recommended in NUREG-0301 is therefore estimated to be about 7 person-years. The cost, including salaries, fringe benefits, administrative support, travel and overhead, is estimated to be about $500,000. This appears to be a modest figure which is believed to reflect the efficiencies of folding this Federal authority into an existing, similar Federal program that also provides for relinquishing authority to qualified States.

These efforts do not include additional effort that will be needed in the initial phases of NRC regulation of NARM, e.g., to locate and educate NARM users.

If existing non-Agreement State licensing programs are recognized and NRC authority over NARM is relinquished in those States as well as in Agreement States, the impact upon NRC will be significantly less. These five States (Illinois, Michigan,* New Jersey, Pennsylvania, and Virginia) currently regulate nearly half of the NARM users in non-Agreement States. The reduction in NRC resources will not be in direct proportion (SD effort would not be significantly altered, for example) but the NRC professional effort required would probably drop to 4 to 5 person-years.

* SP is actively negotiating a Section 274 Agreement with Michigan.

APPENDIX J

Letters to State and Territorial Health Officers, Radiation Control Program Directors, Federal Agencies and NARM Manufacturers and Distributors

APPENDIX J

Letter to be sent to
State Health Officers, State Radiation
Control Program Directors, Federal Agencies
Manufacturers and Distributors

Dear _____:

In July 1977, a Nuclear Regulatory Commission (NRC) Task Force completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC, but NRC has been requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC seek such authority. The Commission recognized the need for input from potentially affected persons, including State and Federal regulatory agencies, and manufacturers and distributors of these materials. A Federal Register notice was published July 21, 1977 which announced the availability of the report for public review and comment. On July 20, 1977, I wrote you informing you of these actions.

Twenty-five public comments were received and have been placed in the NRC Public Document Room. The overwhelming majority (84%) expressed some measure of support for the Task Force recommendation.

I wish to now inform you that the Commission, after evaluation of the Task Force report and analysis of the public comments has approved the drafting by NRC staff of proposed legislation which would give the NRC authority over these materials.

Should you have any questions, please feel free to contact me.

Sincerely,

D. A. Nussbaumer, Assistant Director
for Material Safety and Licensing
Office of Nuclear Material
Safety and Safeguards

APPENDIX K

Letters to Congressional Committees

APPENDIX K

Letter to Congressional Committees

Dear _____:

In July 1977, a Nuclear Regulatory Commission (NRC) Task Force had completed a study on the regulation for health and safety of naturally occurring and accelerator-produced radioactive materials. These materials are not now regulated by NRC, but NRC had been requested by the States to seek authority to regulate these materials.

The Task Force recommended NRC seek such authority. The Commission recognized the need for input from potentially affected persons, including State and Federal regulatory agencies, and manufacturers and distributors of these materials. A Federal Register notice was published July 21, 1977 which announced the availability of the report for public review and comment. A copy of the report is enclosed.

Twenty-five public comments were received and have been placed in the NRC Public Document Room. The overwhelming majority (84%) expressed some measure of support for the Task Force recommendation.

Because of your interest in the control and regulation of hazards from radiation sources, I wish to inform you that the Commission, after evaluation of the report and analysis of public comments, has approved the drafting by NRC staff of proposed legislation giving NRC regulatory authority over these materials.

Should you have any questions, please contact us.

Sincerely,

Lee V. Gossick
Executive Director
for Operations

Enclosure:
As stated

APPENDIX L

OPE Comments and Response

APPENDIX L

Staff Response to OPE Comments

No changes were made to this paper as a result of OPE comments. (Attached). The paper already took note (on p. 5) of the Commission's approval of a staff proposal to draft proposed legislation to give NRC authority to regulate naturally occurring radioactive materials associated with mill tailings in non-Agreement States (SECY-77-303A). Chilk's November 11, 1977 memo to Gossick (attached to OPE's comments) also observed that the Commission has not made a final decision to submit this legislation. Hence, we do not believe the NARM recommendation necessarily complicates the issue. Rather, we believe the Commission should now be provided an opportunity to consider a more comprehensive proposal concerning NRC control over NARM as well as the more limited proposal embodied by SECY-77-303A. The proposed legislation for mill tailings would be consistent, in principle, with the recommendation of the NARM task force.

OPE expressed concurrence with ELD's comments concerning the possible impact of the extension of NRC jurisdiction on other agencies and suggested the Commission may wish to consider a broader study treating reorganization of existing radiation protection authorities. The recommendations of the NARM task force were developed in response to requests from the States for specific, limited action by NRC: To exert control over NARM. We were not requested to seek a broad reorganization of radiation protection authorities. A broader study as proposed may be warranted but would seem to more properly be in the province of Congress or the Executive Office.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

March 31, 1978

MEMORANDUM FOR: Tom Rehm

FROM: Ken Pedersen

SUBJECT: FINAL RECOMMENDATIONS OF THE TASK FORCE REGULATION OF NATURALLY OCCURRING AND ACCELERATOR-PRODUCED RADIOACTIVE MATERIALS (NARM)

I do not concur with the final recommendation of the NARM Task Force to begin to develop a legislative proposal to exert NRC control over NARM, which would include uranium mill tailings. The question of NRC authority with respect to uranium mill tailings is vital and timely and is already the subject of active, concentrated attention by the staff, the Commission and the Congress. On November 11, 1977 the Commission asked the staff to draft legislation providing NRC with regulatory control over mill tailings. (See Attachment A.) We should deal with the mill tailings issue now rather than mixing it in with other kinds of NARM which can only lengthen substantially the time to prepare the legislative proposal, complicate further the issue in terms of Commission and Congressional consideration, and provide additional fronts on which other agencies, particularly EPA and FDA, may oppose us.

With respect to NARM other than mill tailings, I would much prefer them to be treated in an overall study of what the organizational structure for radiation protection at the Federal level should be. In this regard, I concur in part with the ELD note in the Coordination section of the subject paper which notes that because of the impact extension of NRC jurisdiction to include NARM would have on other agencies, the Commission might wish to consider a broader study treating reorganization of existing radiation protection authorities. Such a study should include options which foresee NRC acquiring as well as relinquishing authority where duplication or uncertainty now prevail.

Attachment:
As Stated

CONTACT:
Pat Comella (OPE)
634-1541
George Sege (OPE)
634-1643

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

November 11, 1977

OFFICE OF THE
SECRETARY

MEMORANDUM FOR: Lee V. Gossick, Executive Director for Operations

FROM: Samuel J. Chilk, Secretary

SUBJECT: REGULATORY CONTROL OVER URANIUM MILL TAILINGS (SECY-77-303A)

The Commission has approved the staff's recommendation in SECY-77-303A that the staff develop legislation which would give the Commission statutory authority to regulate mill tailings as a licensable material and which would provide a basis for long-term control of tailings disposal sites following final disposal by the mill operator.

The Commission has not made a final decision to submit this legislation. Furthermore, the General Counsel has raised the issue of, and the Commission has not made a final decision on whether the draft legislation should seek regulatory authority over tailings at inactive sites.* Consequently the staff should:

1. Draft the legislation without "inactive site authority," as proposed by staff. (SECY Suspense: December 23, 1977)

2. Draft a separate insertable statutory section which would provide for authority over inactive sites. (December 23, 1977)

The staff paper putting forward the draft legislation should reflect OGC and OPE views on the inactive sites issue and should also contain the staff's recommendation on whether the Commission should seek such authority. That staff paper should also discuss and take into account DOE's course of action for inactive sites.

*See attached memorandum from OGC to the Commission dated October 26, 1977.

cc:
Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
General Counsel
Director, Policy Evaluation
Director, Congressional Affairs
Director, NMSS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

October 26, 1977

MEMORANDUM FOR: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford

FROM: Jerome Nelson, General Counsel

SUBJECT: COMMENTS ON SECY-77-303A, "REGULATORY CONTROL OVER URANIUM MILL TAILINGS"

Although I agree with the legal analysis presented in SECY-77-303A, I am not ready to concur in the staff's recommendation that legislation proposed to give the NRC direct statutory authority over uranium mill tailings should specifically exclude tailings at the inactive sites covered by ERDA's remedial action program. Putting such a limit on the proposed new authority would take away most of its potential usefulness. As the paper notes, under the Atomic Energy Act and NEPA, the NRC already has ample authority to regulate the handling of tailings at active sites and to condition issuance of new licenses on adequate provision for disposal of the tailings.[1] This authority is "unclear" only in the sense of being indirectly rather than explicitly derived from the statutes. Apart from clarification, the main benefit NRC would derive from the legislation which the staff proposes would be authority to maintain control over tailings disposal sites after the mill operator has completed all the disposal actions required by the licensing conditions. Such authority could be useful, as the staff paper observes, "to assure the disposal sites are not disturbed over the long term." But this problem of potential disturbance at disposal sites lies relatively far in the future, and does not afford much incentive to push for new authority right now.

---

1 SECY-77-303A points out that requiring surety arrangements at time of licensing compensates effectively for any practical limitations on the NRC's ability to enforce these conditions years after milling operations cease.

Contact:
E. Leo Slaggie
254-8017

In contrast, problems with tailings accumulations are current and pressing at presently inactive and abandoned sites, where it is reasonably clear that NRC has no regulatory authority, either direct or indirect. Here the need for direct authority over tailings is potentially the greatest. The staff argues that ERDA's recommendations for remedial action at these sites are imminent and that in some unspecified way "[f]or NRC to attempt to exercise regulatory control over these tailings ... would serve to complicate an already difficult situation and to possibly delay initiation of the remedial actions." I believe that the appropriate response to this argument is to wait and see what ERDA comes up with rather than go to Congress now with a legislative proposal which omits authority the NRC might later wish it had. It may turn out that the remedial action ERDA proposes will in fact call for NRC authority over tailings at abandoned sites. Alternatively, the Commission may find that the ERDA proposals fall short of what the Commission believes necessary to cope with health and safety problems associated with exposed tailings piles (for example, long-term population dose from radon emissions). The Commission might then choose to seek the additional authority necessary to set up an adequate remedial program. Either way, a premature commitment now to a limitation on proposed NRC authority over mill tailings would reduce the Commission's ability to respond later on to potential developments in the abandoned site tailings problem.

Since, apart from this question of tailings at abandoned sites, there appears to be no urgent need for new legislative authority over mill tailings, I suggest that the submission of the proposal to Congress be deferred until the ERDA recommendations are available and the draft GEIS on uranium milling is substantially complete, probably by fall of 1978. Having this deferred submission in mind, the staff can adjust its efforts appropriately for the development of a legislative proposal. In my view, the new legislation should include NRC authority over tailings at sites now inactive, but should embody sufficient flexibility that the NRC could choose not to exercise this authority, should such a policy turn out to be desirable as an accommodation to ERDA or perhaps EPA.

cc: OPE (2)
SECY (2)